BOOSTB4

Boost Brittle Bones Before Birth

A clinical research trial of a new intervention for brittle bone disease

Participant information Prenatal (before birth) Trial Group

Participant information for the BOOSTB4 clinical trial

You have recently been informed that your unborn child may have brittle bone disease (Osteogenesis Imperfecta, OI). We understand that this is a difficult situation for you.

We are conducting a clinical trial with the aim to improve the health of children with OI. The intervention will start before, or soon after, birth. This is why you have been given this information. You can read more about the trial below. If you decide you do not want your child to take part in the trial, we would still like to collect information about your child, with your agreement. If you have any further questions about OI or about the trial, please ask your doctor.

Important things you need to know

- Please take time to read the following information carefully. Discuss it with your partner, relatives and friends if you wish. Take time to decide whether or not you wish to take part.
- You are free to decide whether or not to take part in this research trial. If you choose not to, this will not affect the care you receive from your doctors in any way.
- You can stop taking part in the research trial at any time, without giving a reason.
- Ask us if there is anything that is unclear or if you would like more information.
- If you decide to take part you will be asked to sign a consent form. You will get a copy of this information and the conent form to keep.

Summary of the research trial

- We want to find out if stem cell infusions can improve the health of babies with OI, brittle bone disease, without risk to the mother or the child.
- The trial is called BOOSTB4 (Boost Brittle Bones Before Birth).
- The stem cell infusion will be given to unborn babies diagnosed with OI as an injection through the mother's womb into the baby's umbilical cord. Three more infusions will also be given into the baby's blood after the baby is born.
- The stem cell infusion used in this trial has been given to babies inside the womb and children before with promising results and without any apparent harm. However, as with all new treatments, more evidence is needed to show that it is safe and effective.
- This trial will require you to visit the hospital more times than if you and your baby with OI were being looked after in the usual way.

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How to contact us

If you want further information about the BOOSTB4 trial, contact a trial doctor:

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You are also welcome to contact the coordinator for the trial:

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More information is also available on our website: www.boostb4.eu

1 Why are we doing this clinical trial?

What is OI?

Osteogenesis Imperfecta (OI), or brittle bone disease, is a condition where collagen, the protein that is responsible for bone structure, is low or of poor quality. The minerals in the bone are therefore not supported, making the bone weak and in turn making it fracture easily.

There are four main types of OI:

Type 1 is often mild and usually not diagnosed until later in childhood.

Type 2 is very severe and means that babies unfortunately do not survive. It is detectable in the womb on ultrasound.

Type 3 and the severe forms of Type 4 are possible to detect whilst the baby is in the womb, or shortly after birth. These types of OI result in numerous fractures, stunted growth and pain.

In order to know for certain that a person has OI, a DNA test must be performed. This can be carried out on a sample of amniotic fluid or placenta or from a blood test once the baby is born.

If you want to know more about OI, please talk to the doctor who is treating you.

How is OI usually treated today?

There is no cure for OI, but there are some treatments that can help reduce the symptoms of pain, fractures and bone deformation.

Current treatments can only be given after the baby is born.

The main treatment is a drug called bisphosphonate, which prevents loss of bone mass by improving the imbalance between bone loss and formation which occurs in OI, thus it strengthens the bone by increasing bone density. The bone will however still fracture more easily than normal bone. Children with moderate to severe OI are normally given bisphosphonate infusions regularly.

Fractures are treated according to the advice from the orthopaedic doctors. Sometimes metal rods are inserted inside the larger bones.

If you take part in the trial, all of these current treatments will still be offered.

What are we trying to find out?

Stem cell infusion with cells that have the potential to make bone is a possible new treatment for OI.

The main thing we want to confirm in this trial is whether the stem cell infusion is safe to use in pregnant women, their babies, and children with OI.

We also want to evaluate if the stem cell infusion improves the health of children with OI. Specifically we want to investigate if the number of fractures and chronic pain can be reduced and growth can be improved.

If this study is successful we aim to develop the stem cell infusion as a future clinical treatment for OI.

2 Why am I being asked to take part?

You are being asked if you would like to take part in the BOOSTB4 (Boost Brittle Bones Before Birth) trial because your unborn child may be suffering from OI type 3 or severe type 4.

3 What do I need to know about the stem cell infusions in this trial?

What are stem cells?

The human body is made up of many different kinds of cells such as muscle cells, nerve cells and bone cells. Stem cells are primitive cells

that can develop into these different specialized cell types.
There are several different types of stem cells. 'Mesenchymal stem cells' are the specific type of stem cells used in the BOOSTB4 trial as they can become cells that make bone, cartilage and muscle. These stem cells are special because data so far show they do not cause an immune reaction and they are very unlikely to lead to the development of cancer.

The stem cells for the BOOSTB4 trial are prepared from fetal tissues obtained during legal terminations of pregnancy performed before 12 weeks' of pregnancy in Sweden. Women undergoing the terminations have given their approval that the stem cells can be used in this trial. Research has shown that fetal stem cells are able to form bone better than stem cells from adults. We also believe that giving fetal stem cells to an unborn baby can give a better clinical result, compared to if adult cells are given.

We believe that if we give these stem cells to a baby with faulty bone making cells, the stem cells may travel to their bone and become new bone producing cells. These may make healthy collagen which can support the damaged bone and help to develop normal new bone.

What has previously been done?

More than 15 years ago, a trial was performed in the USA where six children were treated after birth with two infusions of adult mesenchymal stem cells. One treatable allergic reaction (hives) was observed after one of the 12 infusions. No other side effects were noted. The children did well with improved growth and reduced number of fractures.

Researchers within the BOOSTB4 consortium have previously given fetal mesenchymal stem cells to four children with OI. The children received an infusion of the stem cells after they were born or as an unborn baby while they were in the womb. The children have received further booster doses of the same stem cells after birth. Clinically, they did well after the stem cell infusions, growing better and having fewer fractures and less pain than would have been expected. Looking through a microscope at bone samples, we could see that the stem cells had engrafted (settled) into the bone and become bone producing cells. By 2018 the treated children were between 3 and 16 years old. No side effects have been detected so far. However, the number of babies treated so far in the world is only ten.

Studies in animals suggest that stem cells given early in life reduce the number of fractures and help bones become stronger. We therefore believe that an early intervention could lead to better results.

Will everyone receive the stem cells?

All patients who are eligible and want to participate will receive stem cells. There will be two different trial groups who receive the stem cell infusion in this trial. The study does not have a placebo group (inactive medicine) and there will be no randomisation.

The prenatal trial group consist of pregnant women who, like you, have an unborn baby with a diagnosis of OI. In these women, the first dose of stem cells will be given as an injection through their abdomen and womb into the umbilical cord of the baby, between 16 and 35 weeks of pregnancy. Three further stem cell infusions into the child's blood will be given 4, 8 and 12 months after the first infusion. Six and twelve months after the last infusion there will be a follow-up and the last blood samples taken from your child for the trial. After this, your child will then see his/her OI Specialist doctor every year for up to 10 years after the first infusion, as the child would normally do. We will ask you to fill out a health questionnaire every year for 10 years.

The postnatal trial group is made up of babies who will only receive infusions after birth. In this group, four infusions of the stem cells will be given every four months. The postnatal trial group will not receive the stem cell infusion in the womb.

We will compare babies and children who receive the stem cell infusions with children with OI who have not had stem cell infusions.

Which group will I be in?

If you are eligible to take part in the trial, we would like to include you and your baby in the prenatal trial group, where your baby will receive one stem cell infusion before birth and three stem cell infusions after.

If you do not wish your baby to have the stem cell infusion in pregnancy, another option is to include your child in the postnatal trial group, with four stem cell infusions given in early childhood.

If you decide not to take part in the trial but you are happy for us to collect information about your pregnancy and your baby after birth, we would like to include your baby in the comparison non-infusion group (BOOSTB4 Prospective Study). This group will receive the routine treatments.

You may decide not to continue with your pregnancy. We understand that this is a very difficult decision for you to make. Please talk to your doctor if you think this may be the best option for you and your family.

4 What will I need to do if I take part?

Can I take part?

Not everyone will be able to take part in this research trial. We need to perform an assessment first to see whether you are eligible.

On your initial visit to a BOOSTB4 centre we will ask you to sign a consent form for screening. This will give us permission to check your medical records and perform an ultrasound scan to assess your unborn baby. We will also review the result of your amniocentesis (sampling of amniotic fluid) or CVS (sampling of the placenta) test to confirm the type of OI your baby has.

If you have not already received a genetic diagnosis for your baby, we will need to carry out an amniocentesis and take some blood tests from you and your partner before you can take part in the trial. Together these will be used to confirm that your baby has OI.

When we have the results of these screening investigations we will be able to let you know if you meet the eligibility criteria and can take part in the research trial.

Optional: Non invasive prenatal testing

An optional part of the trial is to help us develop a way to test if an unborn baby has OI, without having to take a sample from the baby. We will do this by testing the baby's genes in the maternal blood. We are already able to identify the baby's sex, blood group and some genetic conditions and chromosomal problems such as Down's syndrome using this test.

We ask you to donate an additional maternal blood sample (20 mL, less than 2 table spoons), which we aim to take at a time when other blood samples are being obtained. We would also like to collect a sample of blood (5 mL, 1 tea spoon) from the baby's father to help us develop this test. We are also asking your permission to use any excess cells grown in the laboratory after your amniocentesis/CVS to help evaluate the new tests. If your amniocentesis/CVS was already performed at a different hospital, we can speak to the laboratory and arrange for the cells to be transferred to us. We are not asking permission to take any extra amniocentesis/ CVS samples or to repeat the procedure.

We hope that the results of this part of the study will enable us to develop a non invasive prenatal test for OI. It is up to you to decide whether or not to take part in this section of the trial. If you do decide to take part you will be asked to sign an additional box on the consent form. We will also need the baby's father to sign a consent form to say he is happy to donate his blood sample. If you decide to take part and donate the additional blood sample you are free to withdraw at any time

without giving a reason. If you do not wish to take part in this section of the trial it will not in any way affect the care you or your family receives. You will still be able to take part in the main BOOSTB4 trial.

What if the tests show I can take part in the trial?

Once we know you are eligible to take part in the research trial we will ask you to meet with different specialists. Your Fetal Medicine Specialist will talk you through the in utero stem cell infusion procedure and explain about the care for the rest of your pregnancy. We will arrange a meeting with a paediatrician who looks after children with OI, so that you can find out what to expect once your baby is born. They will be able to let you know about the practicalities of the postnatal infusion process and will be able to answer any questions about OI that you may have. Finally we will ask you to discuss your decision with a counsellor to check that you do not have any unanswered questions. We would like you to take at least three days to consider your decision before you sign the second consent form. This is to make sure that you do not feel rushed and that you can ask all the questions you want about the trial.

What will happen to me during the trial?

A few weeks before the infusion you will need to have an antibody blood test to ensure it is safe to give the infusion. This blood test can be performed at your local hospital if it is easier for you.

On the day of the procedure we will carry out another ultrasound scan of your baby. We will also check your wellbeing by monitoring observations such as your heart rate and temperature and take a blood sample, to make sure it is safe to go ahead with the stem cell infusion.

We perform the prenatal infusion of stem cells under ultrasound guidance to ensure we guide the needle to the right place. This technique has been used for many decades to give blood cells to unborn babies in the womb who have anaemia. The doctors that perform the injection are very experienced.

First, we will clean your abdomen with a sterile solution. Then we give you some local anaesthetic to your skin to numb it. Finally we will insert a fine needle through your skin to the inside of your womb, into your baby's umbilical vein. We give your baby sedation to temporarily reduce their movements. After taking a small sample of your baby's blood we will infuse the stem cells. We will monitor your baby continuously with ultrasound during and for two hours following the procedure. We will monitor you as well to make sure you are not suffering from any side effects.

We will then continue to monitor you and your baby's wellbeing regularly until 48 hours after the infusion. Monitoring of your baby will include regular ultrasound scans and heart rate assessments if you are over 26 weeks pregnant. Monitoring of your wellbeing will include checking your observations regularly and taking 4 blood tests. Because pregnancy is a time where you are at increased risk of blood clots, we will ask you to stay well hydrated and mobile, and give you blood thinning injection whilst you are in the hospital to keep this risk as low as possible. You should be able to go home 2 days after the infusion.

We will perform an ultrasound scan around every two weeks following the procedure so that we can look at the growth of your baby and monitor any fractures. If it is not possible for you to travel to the BOOSTB4 centre for these visits, we can arrange for these scans to be performed at your local Fetal Medicine Centre.

As we would for all babies with OI, we strongly recommend your child is delivered by Caesarean section. This is likely to be more gentle on your baby's brittle bones than a vaginal delivery. At the time of the delivery, we will collect samples of amniotic fluid, placenta, umbilical cord, cord blood and a blood sample

from you. We will also take a blood sample from you four months after your baby is born (at your child's routine hospital visit). This is to study any immune response to the stem cells. If this is normal we will not require any further tests from you, but we will ask you to fill out a health questionnaire every year for 10 years. We would also like you to inform us of any future pregnancies or allow your doctor to contact us regarding them so that we can monitor your long term health.

What will happen to my child during the trial?

Once your baby is born the paediatric team will carry out an assessment of their bones and general health. This will involve a low dose X-ray. This is all part of normal care for children with OI. Once you and your child have recovered from the birth we will ask you again whether you would like your child to continue in the trial and have the three booster stem cell infusions. We will need to re check that your child is still eligible to take part in the trial. If they are and you agree to their ongoing participation we will ask you to sign another consent form.

The infusions will be arranged to start 4 months after the prenatal infusion. Your child will have a total of four infusions (three after they are born), each given four months apart. The infusions will be carried out in hospital and will require one to two overnight stays.

A few weeks before each infusion your child will need to have an antibody blood test to ensure it is safe to give the infusion. This blood test can be performed at your local hospital if it is easier for you and your child.

On the day of the stem cell infusion we will carry out your child's routine OI follow-up appointment. We will ask you qustions about how your child has been getting along since we last saw him/her. This involves recording if your child has had any fractures or orthopaedic procedures, along with any medications he/she is taking. We will also perform a clinical assessment of your child's development, growth, limb strength and movement. At a few of these routine appointments, children with OI will have an X-ray of their spine and skull and a scan to assess their bone density (DXA scan). No extra radiological examinations (X-rays and DXA scans) will be performed for the trial.

Your child will have blood tests taken to assess the turnover of their bone. All of these assessments and tests are part of the normal care for children with OI. Before the infusion we will also carry out wellbeing checks and a blood test to make sure it is safe to go ahead with the infusion. We will have to wait for the result of the blood test before the infusion can be given. If the blood test results are abnormal, or if your child has a fever on the day, the infusion must be rescheduled.

If your child has an intravenous port we will use it to give the stem cell infusion. If your child does not have one, we will need to put a drip into a vein. The stem cell infusion itself will take around 10-15 minutes. We will monitor your child's wellbeing during the infusion and for 1-2 days afterwards and also taking 2-3 blood tests. You should be able to go home 1-2 days after the infusion.

We would like to learn about your and your child's quality of life and the health resources you use using two questionnaires. They will take around an extra 30 and 15 minutes for you to fill in. You could also be invited to participate in an interview. We would like to take a photo of your child each year to show how they are growing and the shape of their arms and legs.

You will be given a diary for recording your child's events (such as achieving motor milestones, starting to talk, growth, first tooth, medications, physiotherapy sessions, fractures, operations etc.).

Six and twelve months after the last infusion we will ask you and your child to attend a follow-up appointment, which takes place at your child's routine visit. At the 12-month

appointment, the last blood test for the research trial will be taken.

Your doctor will then see your child every year, at least up until 10 years after the first infusion. These appointments will be the routine appointment as described in the paragraph above. The only additional requirement for taking part in this follow-up is filling in the quality of life and health resources questionnaires at each appointment.

If you decide to participate, it is possible that your child cannot participate in other clinical trials up to 12 months after the last infusion.

Who will be my main contact?

To make sure that you receive the best possible information during the trial you will have close contact with a dedicated team and you can contact us at any given time.

5 What are the possible risks?

There may be unknown risks that we are not aware of. Below we have listed known and theoretical risks.

Possible risks of the prenatal infusion procedure (the way that the medication is given)

These risks are well known and the same as when carrying out invasive procedures in pregnancy such as fetal blood transfusions. A recent large study shows the complication rate for such infusion procedures is 1.2% (12 in 1000), and the risk for missacarrige is 0.6% (6 in 1000).

- Miscarriage
- Premature labour
- Water breaking prematurely
- Infection of the womb
- Your unborn baby suffering a serious drop in their heart rate

If your baby is developed enough to survive outside the womb, an emergency delivery could be performed if any of these rare complications occur. However, this would not be without its problems. Your doctor will discuss with you what you would like to happen in this circumstance.

Maternal complications of invasive procedures in pregnancy are rare (<0.1%, i.e. 1 in 1000, per risk) and include discomfort and/or pain, bowel injury and bleeding.

Possible risks of the stem cell infusion (the medication itself) to you or your child

One treatable allergic reaction (hives) has been reported in a child after infusion of mesenchymal stem cells for treatment of OI. None of the following has been observed in the treatment of 10 unborn babies and children. The risks include:

- Immune reaction
- Blood clots
- Cancer
- Other diseases. We test for bacteria, mycoplasma and viruses such as Hepatitis, HIV, HTLV, CMV, Zika, Parvo- and West Nile virus to make sure the cells are safe to use.

Since cells are naturally transfered between the mother and the baby during a pregnancy, the risks above also apply to the mother.

From what we know today, we believe that the risk of these side effects is very low.

Possible risks of imaging methods (X rays and DEXA scans) to your child

The radiological examinations involved in this study are part of your child's routine care. If your child take part in this study he/she will not undergo any additional radiological examinations. These procedures use ionising radiation to form images of the body and provide the doctor with other clinical information. Ionising radiation can cause cell

damage that may, after many years or decades, turn cancerous. The chances of this happening to your child are the same whether they take part in this study or not.

If you have any concerns at all, please tell the trial staff as soon as possible. We want to hear from you.

6 What are the possible benefits of taking part?

Our goal is that your child will be helped by having the stem cell infusions, but this cannot be guaranteed. We hope that:

- Your child will have fewer fractures

- Your child will have less chronic pain

- Your child's height will be improved

All children taking part in the trial will receive four doses of the stem cell infusion. If the outcome of the trial is that stem cell infusion helps in OI, we may be able to offer further infusions to your child in the future, but we cannot guarantee this.

It is important to remember that the stem cell infusion is not a cure. Your child will still be affected by OI.

The information we get from this trial may also help us to improve treatment for individuals with OI in the future.

The development of a non invasive prenatal test for OI from a maternal blood sample will improve antenatal care for other pregnant women in the future.

7 What are the disadvantages and risks of taking part?

If you decide to participate, it is possible that your child cannot participate in other clinical trials up to 12 months after the last infusion
Other disadvantages to taking part in this trial are:

Infusion procedure

Risks of the infusion procedure are listed in section 5.

Stem cell infusion

Risks of the stem cell infusion are listed in section 5.

Blood samples

You will be asked to have blood tests several times in the trial (five to six times).
After birth, if your baby does not have an intravenous port, they will need to have a drip put in their veins several times in the trial. The same drip line as for the routine bisphosphonate infusion will be used. Having a drip or blood taken can be painful and can leave a bruise, however in children we usually numb the skin with topical local anaesthetic cream first, or we give your child general anaesthesia for the time needed to place a drip. Blood samples for your child's routine care will always be prioritised, and samples for the clinical trial will only be collected if acceptable according to hospital guidelines. Routine care and trial specific blood samples will be taken from your child at the six visits.

The total amount of blood that will be taken from you during the trial is around 70 to 100 mL (at the most 100 mL). The optional blood sample for development of non invasive prenatal testing for OI is 20 mL (less than 2 table spoons).

The total amount of blood that will be taken from your child throughout the duration of the trial is around 10 to 70 mL (between 1 and 5 table spoons).

Amniocentesis or CVS

You will be required to have an amniocentesis (sampling of amniotic fluid) or CVS (sampling of the placenta) test before joining the trial. This is so that we can confirm that your baby does have a diagnosis of OI. This test involves a thin needle being inserted into the womb to take a sample of amniotic fluid or placenta and

carries a small risk of miscarriage (1 in 100, or 1%). This would be recommended whether you chose to take part in the trial or not.

Samples at delivery

We strongly recommend for your child to be delivered by Caesarean section whether you take part in the trial or not. Collecting the samples of amniotic fluid, placenta and cord blood at delivery will not result in any additional procedures to you or your baby.

Time and inconvenience

Visits and infusions will be coordinated to take place at the same occasion as your child's routine OI assessment. Taking part in this trial will place some demands on your time, including:

- The time needed for the screening assessments, including a discussion with a counsellor
- Overnight admission to hospital
- Extra ultrasound scan appointments during your pregnancy
- Extra follow-up appointments and telephone calls

8 More information about taking part

Do I have to take part in the trial?

No, it is up to you to decide whether you wish to take part in this research trial.

If you decide not to take part in this trial, you will receive the standard treatment. Your decision will not affect the standard of care you receive.

Can I stop taking part after I have joined the trial?

You can stop taking part in the trial, or any part of it, at any time and without giving a reason. If you withdraw from the research trial after you have had the prenatal stem cell infusion we would like to continue collecting information about both you and your child. We will try to do this through your family doctor to avoid having to contact you directly. This is important so that we can monitor your wellbeing and because it helps us to ensure that the results of the research trial are reliable. You can refuse this. Your decision will not affect the care you or your child receive from your doctors in any way.

You can refuse that biological samples are saved. If you have given consent for the sampels to be saved, you have the right to take the consent back. The biological samples from you and your child will in that case be destroyed or anonymised. Information already collected from you and your child will however not be destroyed.

If you want to take back a consent, contact the trial doctor (see page 1 for contact information).

What will happen to the information about me collected during the trial?

If you decide to participate in the trial, we will collect information about you and your child and you and your childs development in a locked database. Only information related to the trial will be collected. The information will be kept so only authorised persons have access to it.

The Karolinska Institutet is responsible for the processing of your personal data. Your contact person for this is the trial coordinator (see page 1 for contact information). The Karolinska Institutet is a government agency and has an obligation to, among other things, comply with the rules for public documents, government archives and public statistics. The Karolinska Institutet will therefore also process the personal data in the ways necessary to be able to comply with applicable legislation.

The information will be coded and then made available (with a code instead of name) to the researchers who are part of the BOOSTB4 study in the United Kingdom, Germany, the

Netherlands and Sweden, as well as national and international authorities and the trial monitors that control the trial's safety. This information may be used in future studies approved by the Ethics Review Board.

The information we collect will be processed in accordance with the EU Data Protection Regulation (2016/679, GDPR), which is available to protect people with regard to the processing of personal data. In accordance with the regulation you have the right to once a year and free of charge request what information that has been recorded about your child and, if necessary, correct any errors. If you want to access the information, contact the trial coordinator (see page 1 for contact information). If you have comments on the Karolinska Institutet's processing of your personal data, you can contact dataskyddsombud@ki.se or +46 8-524 840 00. If you are not satisfied with the response from the Karolinska Institutet, you can contact the Data Inspectorate in Sweden with complaints about the processing of your personal data by the Karolinska Institutet; +46 8-657 61 00, datainspektionen@datainspektionen.se.

The samples taken in the trial are stored coded in a so-called biobank in accordance with the Swedish Biobank Act (2002: 297), which regulates how samples can be stored and used. The biobank's name is the Stockholm Medical Biobank (reg. No. 914). The Karolinska University Hospital is responsible for the biobank.

Samples will be sent to other countries within the EU / EEC for analysis. The code key is stored securely and is only available to authorized persons. The samples may only be used in the manner for which you have given consent. Should there be additional research that is not yet planned, the Ethics Review Board in Sweden will decide whether you should be asked to consent again.

What will happen to the results of the trial?

When the trial is completed, we will publish the results in a medical journal, so that other doctors can see them. You can ask your doctor for a copy of any publication. Your identity and any personal details will be kept confidential. No named information about either of you will be published in any report of this trial.

Who is organising and funding the trial?

This clinical trial is being run by the BOOSTB4 Consortium, a group of doctors and scientists from across Europe with a special interest in stem cell therapy and OI.

Your doctor is not receiving any money or other payment for asking you to be part of the trial.

The trial has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 681045 and from the Swedish Research Council.

Who has reviewed the BOOSTB4 trial?

This trial has been approved by competent authorities such as the Ethics Committee and the Medical Products Agency in Sweden. The trial will be conducted in accordance with EU directive 2001/20/EC and the Declaration of Helsinki. Ask your trial doctor if you want to have more information about this.

What if new information becomes available during the course of the trial?

Sometimes during a trial, new information becomes available about the disease or the investigational medicine (the stem cells in the BOOSTB4 study) that is being studied. If this happens, your doctor will tell you about it and discuss with you whether you want to continue the trial.

Your doctor might also suggest that it is in your best interests to stop taking part in the trial.

Your doctor will explain the reasons behind this.

In either case, your doctor will arrange for your care to continue outside of the trial.

What happens if the trial stops early?

Very rarely a trial is stopped early. If this happens, the reasons will be explained to you and your doctor will arrange for your care to continue outside of the trial.

Insurance

All patients that participate in the study in Sweden are covered by an insurance.

If you have a private medical insurance or require travel insurance, your policy may be affected. You should check this with your insurance provider.

What if something goes wrong for me or my child?

If you have any concerns about the way you or your child have been approached or treated during the trial, please talk to your trial doctor. If you are still unhappy, or if you wish to complain, please use the regular hospital complaints process.

If you are harmed by taking part in the trial, or if you are harmed because of someone's negligence, then you may be able to take legal action.

Compensation

No compensation is available for your participation in the clinical trial. We are also unable to fund your travel and accommodation costs. You may be able to obtain support in paying these costs from local/national charities.

OI Support Group

If you want to find out more about OI you can contact: Osteogenesis Imperfecta Federation Europe (OIFE): www.oife.org

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Thank you for taking the time to consider taking part in the BOOSTB4 trial.
