



## **Invitation to take part in a research project**

### ***”Does botulinumtoxin A (botox) make walking easier in children and adolescents with cerebral palsy?”***

We wonder if you would like to participate in an investigation of how botox works.

As you know, a lot of children and adolescents with CP experience difficulties in walking. Some may stumble easily, walk on toes, get tired quickly or experience difficulties while walking on uneven surfaces like gravel roads or paths. This can make it difficult to participate in leisure time or school activities with friends.

The doctors think that you may benefit from injections with botox in the calf muscles. This treatment is supposed to make walking easier for you. You may have had injections with botox earlier. In such case, if you had a tendency to walk on your toes, these injections might have made it easier for you to walk on the whole foot. However, this effect lasts only for a few weeks. We want to investigate if treatment with botox actually makes walking easier for you and results in you putting less effort. Today, it is not known for sure if botox has this effect.

The best way to find out more about this, is to give half of the participants in this investigation injections with saline instead of botox in the calf muscles. Neither you, nor the doctor who administers the injections or the study team performing the testing on you afterwards, will know if you received saline or botox. This will be kept a secret. Before you get the injections, and later in the first, third



and sixth month thereafter, we will investigate how easy it is for you to walk.

When all the participants have been tested, it will be known who received botox and who received saline. This way, we will find out if botox makes walking easier. Especially, we are also interested in finding out how long does the botox effect last. Because of that, it may take up to half a year before you have injections with botox again.

Do you want to participate in this investigation?

If you say yes, you will have to visit the hospital four times for different investigations. These visits will be once before the injections and then in the first, third and sixth month afterwards. Among other things, we will then investigate your muscle strength and your walking pattern. This will not be uncomfortable or painful, but it will take 1,5-2 hours.

Both injections with botox and saline can be painful, but you can have local anesthesia to prevent this. Some may feel tenderness in the muscles after the injections, but most notice little or nothing afterwards. A few times, the skin surrounding the injection sites can get red, swollen and warm. If that happens, a doctor should investigate if further treatment is necessary.

The results from this investigation will be anonymous. This means that when we publish articles about the findings in journals, no one will know who you are. Even if you say yes to participation, you can at any time change your mind. You do not have to give a specific reason as to why.

If you have questions, you or your parents can call either

- Anne Elisabeth Ross Raftemo, Vestfold Hospital Trust, tel.: 92064296

or



- Siri Merete Brændvik, St. Olavs hospital, tlf.: 72573830 / 93426016

Check out the study's homepage on <https://stolav.no/WE-studien>.