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Deep Brain Stimula-
tion for Patients with
Incomplete Spinal
Cord Injury for Im-
provement of Gait

What is a clinical study?

Every kind of examination of patients with the purpose to gain new insights in diseases and their treatment is a clinical study. Participants in clinical studies are volunteers, that sign an agreement form to participate after careful information. Studies are closely observed by the authorities (cantona ethics committee). All surveyed data are strictly confidential.

What is the DBS-SCI study about?

We aim to evaluate, if electrical stimulation of a certain region of the midbrain leads to improvement of the ability to walk in patients with spinal cord injury. Earlier studies in animal models have shown this effect. Stimulation of this region in patients with Parkinson's disease have proven an effect on balance and gait. The surgical technique is the gold-standard therapy for other indications today (Parkinson's disease, essential tremor and other movement disorders) and was applied to more than 200.000 patients all over the world until today.

Who can participate?

You may possibly be eligible for participation in the study if you

- suffered an injury of the spinal cord above the level of the 10. vertebral body,
- the injury lies back at least 6 months and rehabilitation is finished,
- you can cover a distance of at least 10 meters with the assistance of crutches/a walker and/or an assisting person.

Participation in the study is voluntary and can be cancelled any time without the need to give reasons and without disadvantage for your medical treatment. Participation is free of charge and will also not be compensated.

What happens in the study?

After careful selection of the participants according to defined criteria and after written informed consent, comprehensive examinations are performed such as walking tests, blood examinations, cranial MRI (magnet resonance tomography), measurement of brain activity and others.

During an in-hospital stay of about 2 weeks, an awake surgery is performed unilaterally with implantation of an electrode in the midbrain. The surgery is followed by numerous tests to show, if the stimulation does positively affect the ability to walk. If this can be shown, an impulse generator will be implanted under the skin permanently. After 2 weeks, 1 months, 3 and 6 months follow-up examinations will be performed to evaluate the treatment result.

What are the benefits for you?

- There is a chance to improve your ability to walk through this treatment.
- You support the development of a new treatment option for patients with spinal cord injury.

Is it dangerous?

- Although the treatment is in very similar to the standard treatment for other diseases, there is a small surgical risk to be considered.
- It is possible that the treatment will not work.
- The clinical examinations may be taxing for you.

Who will answer your questions during the study?

Whenever you have questions, both study nurses and the participating physicians will provide sufficient time to discuss all steps of the therapy and examinations with you.

Where do I find further informations?

For further informations please refer to our web-page:...

Alternatively you can contact us under the overleaf address and numbers.