ISRCTN18539256 https://doi.org/10.1186/ISRCTN18539256

Nerve reconstruction with NeuraGen® nerve conduits

Submission date	Recruitment status
27/02/2008	No longer recruiting
Registration date	**Overall study status**
04/06/2008	Completed
Last Edited	**Condition category**
29/01/2019	Injury, Occupational Diseases, Poisoning

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
NEU-112-LOH-1923-J

Study information

Scientific Title
Prospective cohort study to evaluate factors for the therapy results after nerve reconstruction with NeuraGen® nerve guide

Study objectives
The objective of the clinical study is the evaluation of the nerve regeneration after nerve reconstruction of the sensible nerves of the digits with the NeuraGen® nerve guide. The main clinical objective will be the return of sensibility which will be assessed after different time-points.

The general purpose is to specify the perspective of successful nerve regeneration after nerve reconstruction with the NeuraGen® nerve guide in a large population to support former findings in smaller populations.

There is no control group within this study. The results of this study will be compared with data found in published material. Also, the influence of different parameters on the clinical outcome (e.g. age, gender, concomitant injuries) will be examined.

As of 05/01/2012, the anticipated end date was changed from 28/02/2011 to 30/04/2012.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Institutional Review Board of the University Medical Centre Schleswig-Holstein. Date of approval: 10/02/2007 (ref: 07-112)
2. Institutional Review Board of the University Hospital rechts der Isar, Technical University Munich. Date of approval: 12/12/2007 (ref: 1923)

Study design
Observational, prospective, multi-centre cohort study.

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Nerve reconstruction

Interventions
All participants will have nerve reconstruction by interpositional grafting of NeuraGen® nerve guides.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Nerve regeneration at first week post-operation and then 3, 6 and 12 months.

Secondary outcome measures
1. Patient satisfaction at 3, 6 and 12 months (questionnaire)
2. Pain at first week post-operation and then 3, 6 and 12 months (questionnaire)
3. Dysaesthesia at first week post-operation and then 3, 6 and 12 months

Overall study start date
01/03/2008

Completion date
30/04/2012

Eligibility

Key inclusion criteria
1. Both males and females, age 6+
2. Existence of a complete nerve transsection of a sensitive nerve of the hand that cannot be overcome by tensionless nerve coaptation
3. Informed consent to the procedure and the inclusion into the study given by the patient and the parents in case of underage
4. Time interval between primary nerve damage and reconstruction less than 12 months
5. Nerve gap equals or is shorter than 30 mm

Participant type(s)
Patient

Age group
Other

Sex
Both

Target number of participants
100

Key exclusion criteria
1. Polyneuropathia
2. Pre-existing damage to the injured nerve (e.g., trauma or chronic compression disease) - injury at different levels of the nerve
3. Acute local infection
4. The reconstructed nerve cannot be covered with soft tissue
5. Life expectancy <1 year due to malignancy or other systemic diseases

Date of first enrolment
01/03/2008

Date of final enrolment
30/04/2012

Locations

Countries of recruitment
France

Germany

Study participating centre
Technical University Munich
Munich
Germany
81675

Sponsor information

Organisation
Technical University Munich (Germany)

Sponsor details
University Hospital rechts der Isar
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Sponsor type
University/education

Website

http://www.med.tu-muenchen.de

ROR
https://ror.org/02kkvpp62

Funder(s)

Funder type
Industry

Funder Name
Integra Neurosciences (USA)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/05/2014	29/01/2019	Yes	No