ISRCTN61157551 https://doi.org/10.1186/ISRCTN61157551

Effectiveness of the use of a shoulder joint function orthesis" in shoulder joint subluxation after ischaemic brain stroke to avoid post hemiplegics shoulder-hand syndrome

Submission date 07/11/2006	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 13/02/2007	**Overall study status** Completed	
Last Edited 14/08/2012	**Condition category** Circulatory System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Acronym
FOSSIL

Study objectives
Daily use of a shoulder joint function orthesis (Sporlastik) in shoulder joint subluxations after acute, ischaemic stroke can prevent the occurrence of a Shoulder-Hand-Syndrome (SHS) in comparison with a conservatively treated patient sample.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approval received from the local ethics committee (Ethikkommission Bayerische Landesärztekammer) on the 17th October 2006 (ref: 06072).

Study design
Two-armed, randomised, controlled, open trial.

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Ischaemic stroke with hemiparesis of the upper extremity and following shoulder joint subluxation

Interventions
Basic therapy for both groups, fitting of the shoulder joint function orthesis of the experimental group, and no additional measures for the control group.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Primary terminating point:
The sum of SHS scores on the days 14, 21 and 28: x = SHS [d 14] + SHS [d 21] + SHS [d 28]

If a patient doesnt have a follow-up value (after day seven), he will not be considered evaluable. In this case the recruiting for the replenishment of the drop number continues. Otherwise, the definition of the primary terminating point with missing values or potentially terminator point affecting supplementary therapies, the following rules apply:
Missing values, which no raised values follows, are replaced by the last raised value (rational one: with SHS, the score will rather rise as to sink, without SHS, in reverse).

This procedure is conservative: the therapeutic effect is thereby rather underestimated then overrated. If an additional therapy was necessary because of SHS, which potentially affects the SHS Score, then each raised value will be replaced by the last value noted before begin of the therapy, as long as the value is smaller than the last value before therapy (rational ones: without additional therapy the condition would have probably been not better than before the beginning of the therapy; another worsening during therapy, however is considered with this calculation).

Secondary outcome measures
Secondary terminating points:
Are the processes of the SHS score, of the muscle function, the anthropometry and the finger measurement over the four follow-up dates?

Furthermore, the processes of the SHS sub-scores as well as the categorical SHS evaluation will be analysed:
1. Zero to three: no SHS
2. Four to seven: uncertain
3. Eight to 14:SHS

More classifying of the SHS-Scores are formed, if this is put close by the distribution of the score values. Moreover, the data will be analysed in compliance with the four follow-up dates and telephone follow-ups. The entire compliance is formed by summarisation of the ordinal code values of the categories. Long-term terminator points are evaluated and judged by frequency and severances of the SHS symptomatology indicated by telephone follow-up.

Overall study start date
21/11/2006

Completion date
10/06/2007

Eligibility

Key inclusion criteria
1. Immediate ischaemic stroke with hemiparesis of the upper extremity (by Computed Tomography [CT] secured and proven) and following subluxation - immediate is defined within zero to 21 days after appearance
2. Hemiparesis of the upper extremity with a strength degree zero to three
3. Patient must be mobilised a minimum of four hours daily

4. Patients that have given their written consent
5. Patients of at least 18 years of age

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Not Specified

Target number of participants
50

Key exclusion criteria
1. Extreme neglect
2. Severe aphasia
3. Superpose or comatose patients
4. Patients with Passage syndrome
5. Patients that receive opioids and analogues
6. Disturbations in the areas of venous, lymphatic and arterial system within the localisation of the paretic arm, which contraindicates the fitting of the function or thesis
7. Planned or intended accompanied therapy:
a. physical therapy with depth-thermal treatment
b. additional therapy with thermal treatment (warmth/cooling)
8. Functional Electronic Stimulation (FES) of the hemiplegics shoulder
9. Contraindications of the producer:
a. allergic or inflammatory or injured conditioned skin changes (e.g. swelling, redness) of supplying body areas
b. circulation impairments or swelling of the soft, lymphatic tissues
c. neurogen caused disturbances of sensory and skintrophic symptoms in the supplying body region (feeling sensation is disturbed with or without skin damage)
10. Long lasting, continuous immobilisation, in particular with older people
11. Physical, psychological or mental inability to follow instructions

Date of first enrolment
21/11/2006

Date of final enrolment
10/06/2007

Locations

Countries of recruitment
Germany

Study participating centre
von Guttenbergstr.10
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Sponsor information

Organisation
Neurologische Klinik Bad Neustadt GmbH (Germany)

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Sponsor type
Government

Funder(s)

Funder type
Government

Funder Name
Neurologische Klinik Bad Neustadt GmbH (Germany)

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	01/09/2012		Yes	No