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Will patients with severe acquired brain injury develop abnormal joint positions and reduced mobility during hospitalisation at a neurorehabilitation department?

Submission date
05/09/2017

Recruitment status
No longer recruiting

Registration date
12/09/2017

Overall study status
Completed

Last Edited
25/11/2020

Condition category
Injury, Occupational Diseases, Poisoning

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

Plain English summary of protocol

Background and study aims:
Increased resistance when a joint is moved slowly (passive ankle joint stiffness), increased resistance with exaggerated muscle activity when the muscle is stretched at high velocity (spasticity) and decreased joint mobility (contractures) are common symptoms in patients with a brain injury. These symptoms may lead to increased joint stiffness, abnormal joint positions, reduced physical performance and pain. Currently, these symptoms are treated with physiotherapy and antispastic medication. Some challenges, however, exist for the correct diagnosis, choice of treatment strategies, and measurement of the outcome of such strategies. Current scoring scales are, however, unable to adequately measure and discriminate between the different components of reduced joint mobility. Furthermore, it is not clear whether current treatment strategies prevent stiffness, spasticity or contractures. The aim of this study is to make a biomechanical evaluation of the occurrence of spasticity, stiffness and contractures in patients with severe acquired brain injuries.

Who can participate?
Adults (age 18 or older) with severe acquired brain injuries and paresis or paralysis in the lower extremities.
Healthy adults (age 18 or older) with no history of neurological disease or fractures of the lower extremities.

What does the study involve?
Participants are recruited after admission to the department. Participants are tested for their muscle tone and spasticity and provide a blood sample. Participants are also given a portable device to wear on their foot and are asked to performed stretches in both of their left and right ankles. This assesses their ankle joint function. Participants are monitored throughout their hospitalisation and have a follow-up measurement one year after the injury date.

What are the possible benefits and risks of participating?
There are no notable benefits or risks of participating.

Where is the study run from?
Department of Neurorehabilitation, Traumatic Brain Injury, Rigshospitalet (Denmark)

When is the study starting and how long is it expected to run for?
November 2014 to February 2017

Who is funding the study?
1. Institute Produits Synthèse (IPSEN) (Denmark)
2. Association of Danish Physiotherapists (Denmark)

Who is the main contact?
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Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Occurrence of passive ankle joint stiffness, spasticity and contractures in patients with severe aquired brain injury

Study objectives
With biomechanical measurements of muscle function it is possible to evaluate muscle function objectively and distinguish the different components of muscle tonus.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of Copenhagen Denmark, 07/01/2014, ref: H-2-2014-058

Study design
Prospective cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Screening

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Severe aquired brain injury

Interventions
Both healthy adults and adults with severe acquired brain injury are included in this study. Participants are allocated to either the group of patients, if they were diagnosed with a severe acquired brain injury and admitted to the neurorehabilitation ward, or to the group of healthy controls. The group of healthy controls are recruited.

Group 1 Patients with severe acquired brain injury:
Participants in this group attend one test session every week during hospitalization after admission to the neurorehabilitation ward. Furthermore they attend one test session one year after injury date. The total duration of each session is approximately one hour. The test session consists of a subjective, clinical tool to measure spasticity, the Modified Ashworth Scale (MAS) and an objective evalutation of passive and reflex mediated stiffness in the ankle joint plantar flexors by a hand-held device attached under the foot. The device contains a dynamometer, electromyography, accelerometer and a gyroscope. The patient is lying supine in bed. An experienced clinician performs slow stretches of the ankle joint from a plantar flexed position. Afterwards, fast stretches above the stretch reflex threshold are applied. One test session consists of five slow stretches and five fast stretches of each ankle joint. The purpose of this

study is to evaluate the development of contractures, spasticity and ankle joint stiffness in patients admitted to neurorehabilitation. Patients that are included in the study receive the same physiotherapy and medical treatment as other patients at the department.

Group 2 Healthy participants:
Each participant undergo one test session with a duration of approximately one hour. The test procedure is the same as for patients except that healthy participants are not having a subjective clinical evalutation of their muscle tonus (The MAS test).

The group of patients with severe acquired brain injury attended a follow-up test session one year after their injury date.

Intervention Type
Device

Primary outcome measure
1. Passive ankle joint stiffness during both slow and fast dorsiflexions is measured using a biomechanical, hand-held device. Patients with severe acquired brain injuries are measured once every week during hospitalization. One year after their injury date, patients will attend one test session. Healthy controls are measured once.
2. Quantification of the occurrence of muscle contractures from measurements of range of motion is measured using “a hand-held device containing a gyroscope”. Measurements are taken once every week during hospitalization and 1 year after the injury. Healthy controls are measured once during one test session.
3. Quantification of the occurrence of spasticity during hospitalization and one year after the injury is measured using the hand-held device and is compared to the clinical measure of spasticity using the MAS test

Secondary outcome measures
1. Changes in collagen types, actin and myosin involved in construction of muscle tissue “are” measured from a blood sample taken from the patients at the first test session during hospitalization and in the beginning of the test session for the healthy controls. Blood samples are analyzed with the Next Generation Sequencing method.
2. Clinical data is measured during hospitalization:
2.1. Functional independence measure (FIM™)
2.2. Early Functional Abilities (EFA)
2.3. Glasgow Come Scale (GCS)
2.4. Glasgow Outcome Scale-Extended (GOS-E)
3. The amount of physiotherapy and any use spasticity reducing medication “are registered in a database by the clinicians with information on date, type and amount of treatment. Information relevant to the study will then be extracted from the database.

Overall study start date
01/05/2014

Completion date
27/02/2017

Eligibility

Key inclusion criteria

Patients who must meet all of the following inclusion criteria:
1. >18 years
2. Patients with severe aquired brain injury who are admitted to rehabilitation at Department of Neurorehabilitation.
3. Patients with palsy or paralysis in at least one of the lower extremities.

Healthy controls:
1. Healthy adults >18 years

Participant type(s)
Mixed

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Patients: N=32. Healthy controls: N = 15

Total final enrolment
33

Key exclusion criteria
Patients:
1. Patients with fractures of the lower extremities
2. Patients with non-cooperative behavior

Controls:
1. Musculoskeletal disorders.
2. Diabetes Mellitus Type 2.
3. Use of muscle relaxation drugs or neuromuscular blocking agents.

Date of first enrolment
02/07/2014

Date of final enrolment
17/01/2017

Locations

Countries of recruitment
Denmark

Study participating centre

Rigshospitalet
Department of Neurorehabilitation, Traumatic Brain Injury
Kettegård Allé 30
Hvidovre
Denmark
2650

Sponsor information

Organisation
Rigshospitalet

Sponsor details
Department of Neurorehabilitation, Traumatic Brain Injury
Hvidovre Hospital
Kettegård Allé 30
Hvidovre
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2650

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/03mchdq19

Funder(s)

Funder type
Industry

Funder Name
Institute Produits Synthèse (IPSEN)

Funder Name
Association of Danish Physiotherapists

Results and Publications

Publication and dissemination plan

Planned publication in a high impact peer reviewed journal.

Intention to publish date
01/02/2018

Individual participant data (IPD) sharing plan
Data will be stored at Department of Neurorehabilitation, Rigshospitalet, according to the data protecting law. Data is not intended to be public available. The type of data stored is raw data from the biomechanical, hand-held device including angles and forces. Furthermore, clinical data from clinical questionnaires are stored. All data is anonymized and all patients and participants gave their informed consent to participate and that their anonymized data could be published. Any further information about the data can be provided by request.

IPD sharing plan summary
Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/12/2019	25/11/2020	Yes	No