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To evaluate the efficacy, safety and tolerability of Hilterapia® (High Intensity Laser Therapy) in the chronic articular inflammatory processes in haemophilic adult patients

Submission date
27/07/2011

Recruitment status
No longer recruiting

Registration date
13/09/2011

Overall study status
Completed

Last Edited
14/02/2017

Condition category
Haematological Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Haemophilia is an inherited condition that affects the blood's ability to clot, which can lead to bleeding into the joints and inflammation. The aim of this study is to assess the effectiveness, safety and tolerability of high-intensity laser therapy (HILT) for the treatment of joint inflammation in haemophiliac patients.

Who can participate?
Patients aged 18 and over with haemophilia A

What does the study involve?
All participants receive nine applications of HILT (three applications per week over 3 weeks). Pain is assessed before, during and after treatment.

What are the possible benefits and risks of participating?
It is not known for certain whether the participant will benefit, but as HILT is already used successfully in other diseases, it could help. The risks of HILT are the following reactions related to the application area: warm with possibly burning sensation, local sensitivity alteration, tingling, numbness, rush and oedema (build-up of fluid).

Where is the study run from?
IRCCS Ospedale Maggiore di Milano (Italy)

When is the study starting and how long is it expected to run for?
May 2011 to December 2011

Who is funding the study?
Baxter (Italy)

Who is the main contact?
Dr Michele Schino

Contact information

Type(s)
Scientific

Contact name
Dr Elena Santagostino

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
HILT-haemophilia-2011

Study information

Scientific Title
To evaluate the efficacy, safety and tolerability of Hilterapia® (High Intensity Laser Therapy) in the chronic articular inflammatory processes in haemophilic adult patients: an interventional pilot multicentre study

Study objectives
Previous experimental studies (Fortune, 2002) indicate how the laser can be antagonistic to degenerative phenomenon, experimentally induced, to stimulate neo-chondrogenisis with formation of simil-jalina cartilage and to induce synovial hyperplasia; these effects appear to be particularly related to variations in light intensity (power intensity: W/cm2) rather than when supplied in doses (Joule J/cm2).

Ethics approval required
Old ethics approval format

Ethics approval(s)

Ethics Comittee of the Foundation of the Institute of Medical Research of a Public Nature and the City Counil of Milan [Comitato di Etica della Fondazione IRCCS Ca´ Granda Ospedale Maggiore Policlinico di Milano], 22/03/2011

Study design
Interventional pilot multicenter study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Haemophilia

Interventions
Therapy with the equipment ASA-SH1 involves 9 applications (3 applications per week x 3 weeks) of Hilterapia® with the following operating parameters:
1. Fluence: 360 to 760 mJ/cm2
2. Frequency: 10 - 35 Hz
3. Total energy: 500 to 1,500 J
4. Time of application: 6 - 11 minutes
Subjects will be requested to attend 10 clinical visits in total: T1 (screening/first treatment), T2-T9 (HILT application visits) and T10 (final visit).

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Pain will be measured using the Visual Analogue Scale (VAS) score (0 = no pain, 10 = unbearable pain) at baseline (T1), T4, T7 and T10 visits
2. Nieschls Score and the articular state will be measured using Hemophilia Joint Health Score 2.0

Secondary outcome measures
No secondary outcome measures

Overall study start date

15/05/2011

Completion date
31/12/2011

Eligibility

Key inclusion criteria
1. Adult subjects with haemophilia A of any severity with or not suppressant
2. Age more than or equal to 18 years
3. Subjects who have been previously diagnosed with a chronic articular inflammatory process or hematoma
4. Subjects who have signed an informed written consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
15 (11 participants had been recruited by the end of the study)

Key exclusion criteria
Subjects with under way bleeding

Date of first enrolment
15/05/2011

Date of final enrolment
31/12/2011

Locations

Countries of recruitment
Italy

Study participating centre
IRCCS Ospedale Maggiore di Milano
Milan
Italy
20122

Sponsor information

Organisation
Baxter (Italy)

Sponsor details
Piazzale dell'Industria, 20
Rome
Italy
00144

Sponsor type
Industry

Website
http://www.baxter.com/

ROR
https://ror.org/02kf9ya90

Funder(s)

Funder type
Industry

Funder Name
Baxter (Italy)

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