

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

<b>Submission date</b> 27/07/2011	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 13/09/2011	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 14/02/2017	<b>Condition category</b> Haematological Disorders	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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

### Contact details

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## Additional identifiers

### Protocol serial number

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-chondrogenesis 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/cm<sup>2</sup>) rather than when supplied in doses (Joule J/cm<sup>2</sup>).

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Ethics Committee of the Foundation of the Institute of Medical Research of a Public Nature and the City Council 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

### **Study type(s)**

Treatment

### **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/cm<sup>2</sup>
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(s)**

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

### **Key secondary outcome(s)**

No secondary outcome measures

### **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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**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)

**ROR**

<https://ror.org/02kf9ya90>

**Funder(s)****Funder type**

Industry

**Funder Name**

Baxter (Italy)

## **Results and Publications**

**Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**

Not provided at time of registration