A Double-Blind, Double-Dummy, Randomized, Placebo-Controlled, 3-Period, Crossover Study to Investigate the Effects of Ethanol and L-000830982 on Essential Tremor.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22574

Source
Nationaal Trial Register

Brief title
N/A

Health condition

Outpatient intervention study.

Sponsors and support

Primary sponsor: Centre for Human Drug Research

Intervention

Outcome measures

Primary outcome

The sensitivity and specificity of Actiwatch and DynaPort MiniMod in discriminating tremor movements from other movements holding the clinical accelerometry/myography-based tremography as the gold standard.

Secondary outcome

1. Tremor intensity, measured by average acceleration amplitude (ìV);

2. Tremor duration measured by average duration of epochs classified as tremor (sec);

3. Tremor amount, measured by proportion of tremor movements per time unit (min/hr);

4. Tremor Clinical Rating Scale.

Study description

Background summary

In the current study, ambulatory methods for measuring tremor will be compared against a gold-standard laboratory tremography method to determine their utility for outpatient proof-of-concept studies. Additionally, the effects of L-000830982 and ethanol infusion on tremor will be determined and compared to placebo. This will be studied in a double-blind, double-dummy, randomized, placebo-controlled, 3-Period, crossover study.

Study objective

1. The effect of a single oral dose of L-000830982 versus oral placebo and an intravenous infusion of ethanol versus placebo on tremor over a 8-hour period in men and women with essential tremor will be estimated;

2. The sensitivity and specificity of laboratory tremography versus 2 ambulant tremography methods in classifying tremor movements versus other movements over a 8-hour period in men and women with essential tremor will be estimated.

Study design

N/A

Intervention

1. L-000830982 2.0 mg PO or placebo;

2. EtOH, infused at a rate to maintain a plasma concentration of ~0.6 g/L (4 hrs) or placebo

IV.

Contacts

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Eligibility criteria

Inclusion criteria

1. Men and women;

2. At least 18 years of age;

3. Essential Tremor diagnosed by a neurologist;

4. General good health;

5. Tremor symptoms present for > 6 months and relieved by ethanol.

Exclusion criteria

1. Medical condition interfering with clinical evaluations or conduct of the study;

2. Smoking > 5 cigarettes per day;

3. Blood donation > 500 ml in previous 3 months;

4. Particpation clinical trial within previous 3 months;

5. Medication use.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	06-07-2005
Enrollment:	9
Type:	Actual

Ethics review

Positive opinion

Date:	15-09-2005
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL374
NTR-old	NTR414
Other	: P05.058
ISRCTN	ISRCTN71182680

Study results

Summary results
N/A