

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

Submission date 27/01/2006	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 27/01/2006	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 03/07/2009	Condition category Nervous System Diseases	<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

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

Protocol serial number

NTR414; P05.058

Study information

Scientific Title

Study objectives

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

Ethics approval required

Old ethics approval format

Ethics approval(s)

Received from the local medical ethics committee

Study design

randomised, double blind, placebo controlled, crossover group study

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Tremor

Interventions

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 hours) or placebo IV

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

L-000830982, ethanol

Primary outcome(s)

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.

Key secondary outcome(s)

1. Tremor intensity, measured by average acceleration amplitude (iV)
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/hour)
4. Tremor Clinical Rating Scale

Completion date

01/12/2005

Eligibility

Key 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

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key 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 the previous 3 months
4. Participation in a clinical trial within the previous 3 months
5. Medication use

Date of first enrolment

06/07/2005

Date of final enrolment

01/12/2005

Locations

Countries of recruitment

Netherlands

Study participating centre

Centre for Human Drug Research
Leiden

Netherlands
2333 CL

Sponsor information

Organisation
Centre for Human Drug Research (CHDR) (Netherlands)

ROR
<https://ror.org/044hshx49>

Funder(s)

Funder type
Research organisation

Funder Name
Centre for Human Drug Research (CHDR) (Netherlands)

Results and Publications

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?
Study website	Study website	11/11/2025	11/11/2025	No	Yes