ISRCTN71182680 https://doi.org/10.1186/ISRCTN71182680

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

Registration date
27/01/2006

Last Edited
03/07/2009

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Nervous System Diseases

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

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.chdr.nl

Contact information

Type(s)
Scientific

Contact name
Dr S.L. Haas, de

Contact details
Centre for Human Drug Research
Zernikedreef 10
Leiden
Netherlands
2333 CL

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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 measure
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 measures
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

Overall study start date
06/07/2005

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
9

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)

Sponsor details
Zernikedreef 10
Leiden
Netherlands
2333 CL

Sponsor type
Research organisation

ROR
https://ror.org/044hshx49

Funder(s)

Funder type
Research organisation

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

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