A SINGLE-BLIND, RANDOMIZED, ESCALATING MULTIPLE DOSE STUDY (PART 1) AND A SEVEN TREATMENT CROSSOVER BIOAVAILABILITY STUDY (PART 2) OF LT-NS001 AND NAPROXEN ADMINISTERED IN HEALTHY SUBJECTS

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON31529

Source
ToetsingOnline

Brief title
LT-NS001 escalating multiple dose and bioavailability study

Condition

- Other condition

Synonym
Chronic pain

Health condition

Chronische pijn zoals bij Rheumatische arthritis

Research involving
Human

Sponsors and support

Primary sponsor: Logical Therapeutics, Inc
Source(s) of monetary or material Support: Logical Therapeutics Inc

Intervention

Keyword: Bioavailability, LT-NS001, Single-blind

Outcome measures

Primary outcome

-

Secondary outcome

-

Study description

Background summary

-

Study objective

-

Study design

-

Intervention

-

Study burden and risks

-

Contacts

Public
Logical Therapeutics, Inc

255 Bear Hill Rd, 4th Floor
Waltham, MA 02451
USA
Scientific
Logical Therapeutics, Inc

255 Bear Hill Rd, 4th Floor
Waltham, MA 02451
USA

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Healthy subjects
Male, 18-70, inclusive (Part 1)
Male/Female, 45-70, inclusive(Part 2), famales must be post menopausal

Exclusion criteria

Pathology for example Hepatitis B, Cancer or HIV/AIDS.
If you have participated in any other drug investigation within 90 days preceding the start of this study or if you have donated blood within 60 days preceding start of this study or loss of blood of similar volume.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	21-11-2008
Enrollment:	36
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	nvt
Generic name:	LT-NS001

Ethics review

Approved WMO Date:	16-11-2007
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	21-11-2007
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)

Approved WMO Date:	28-02-2008
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	06-03-2008
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	15-04-2008
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)

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
EudraCT	EUCTR2007-006163-71-NL
CCMO	NL20480.056.07