ISRCTN17197655 https://doi.org/10.1186/ISRCTN17197655

Open Label Study of GLYX-13 in Subjects with Neuropathic Pain

Submission date 10/11/2014	**Recruitment status** No longer recruiting	[X] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 24/11/2014	**Overall study status** Completed	
Last Edited 24/11/2014	**Condition category** Signs and Symptoms	

Plain English summary of protocol

Background and study aims
We are studying GLYX-13, a compound that has been administered to more than 500 subjects in other clinical trials. GLYX-13 interacts with a receptor in the brain that is thought to reduce pain intensity. In this study we will administer GLYX-13 by needle into a vein one time each week for 12 weeks, in subjects who have neuropathic pain, including pain due to diabetes mellitus and prolonged pain following shingles. The aim of the study is to assess the impact of GLYX-13 on pain.

Who can participate?
The study is open to participants aged 18-75, with neuropathic pain which has not responded to other drug therapy or who are not taking another drug.

What does the study involve?
Over a period of 12 weeks, participants will come to the study site once a week to receive a dose of GLYX-13 by needle into a vein. Throughout the 12 weeks, they will keep paper pain diaries which involve filling out simple questionnaires about pain intensity, and at the site visit each week, the investigator will ask questions about pain intensity during the past week. At the end of the 12 weeks, we will examine whether GLYX-13 affected pain intensity over the course of the study.

What are the possible benefits and risks of participating?
Subjects may experience less pain while taking GLYX-13. However, this will be the first study in which GLYX-13 is being evaluated for its ability to reduce pain, so we have no existing data about whether you may benefit.
The main risk of participation is related to GLYX-13 being an experimental drug. It has been administered in other clinical trials at dose levels up to 6 times the dose being administered in this trial, with no significant side effects. More than 500 subjects have received GLYX-13, about 200 of them received it weekly for 12 weeks.

Where is the study run from?
10 study sites located throughout the United States.
The study is run by Naurex, Inc, which is the company developing GLYX-13 as a drug.

When is study starting and how long is it expected to run for?
The study will begin in mid-December, 2014 and will run for approximately one year.

Who is funding the study?
Naurex, Inc.

Who is the main contact?
Ronald M Burch MD PhD, Chief Medical Officer, Naurex, Inc.
ronburch@naurex.com

Contact information

Type(s)
Scientific

Contact name
Dr Ronald Burch

Contact details
433 West Morris Road
Morris
United States of America
06763
-
ronburch@naurex.com

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
GLYX13-C-204

Study information

Scientific Title
Open Label Pilot Efficacy and Safety Study of GLYX-13 in Subjects with Neuropathic Pain

Acronym
N/A

Study objectives
This study will examine whether GLYX-13 reduces pain in subjects with neuropathic pain.

Ethics approval required

Old ethics approval format

Ethics approval(s)
Quorum Review IRB, 30/10/2014, ref. QR29955

Study design
Open-label interventional trial to study GLYX-13 in subjects with neuropathic pain at up to 10 sites and 100 subjects.

Primary study design
Interventional

Secondary study design
Non randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Neuropathic pain including post-herpetic neuralgia, diabetic neuropathy

Interventions
Subjects will receive a dose of GLYX-13, a drug that controls the level of activity of NMDA receptors in the brain. All subjects will receive one dose of GLYX-13 into a vein one time each week for 12 weeks.

Intervention Type

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
GLYX-13

Primary outcome measure
Daily Assessment of Average Pain Intensity (DAPI) at the end of the study compared to the week prior to first dose of GLYX-13. The DAPI reports the worst pain during the day with pain being recorded upon waking up, at mid-day, and prior to going to bed. Pain will be rated using an 11-point scale with "0" being no pain to "10" being worst pain imaginable.

Secondary outcome measures
Daily worst pain:
1. Change in Brief Pain Inventory (BPI), a questionnaire
2. Neuropathic Pain Symptom Inventory (NPSI), a questionnaire

3. Mean Daily Sleep Interference Score (DSIS), a scale from "0" - no interference with sleep to "10" - interferes with sleep always
4. Patients Global Impression of Change (PGIC), a quiestionnaire
5. Change in consumption of concomitant pain medication, writing down the other pills taken to reduce pain

Overall study start date
15/12/2014

Completion date
30/12/2015

Eligibility

Key inclusion criteria
1. Male and female subjects
2. 18-75 years of age
3. Currently taking pain medications but pain is not adequately controlled, or currently not taking pain medication due to intolerance or lack of efficacy
4. Subjects who have experienced neuropathic pain not excluded in the exclusion criteria for 6 months or longer with pain score of 30/100 or greater by VAS at screening visit.
5. Female subjects of childbearing potential with a negative serum pregnancy test prior to entry into the study and who are practicing an adequate method of birth control (eg oral or parenteral contraceptives, intrauterine device, barrier, abstinence) and who do not plan to become pregnant during the course of the study. Female subjects may be included without a negative serum pregnancy test if they are surgically sterile or at least 2 years post-menopausal.
6. Male subjects who are abstinent during the course of the study or who use a condom during sexual intercourse.
7. Clinical laboratory values <2 times the upper limit of normal (ULN) or deemed not clinically significant per the investigator and Naurex medical monitor
8. Ability to understand the requirements of the study, provide written informed consent, abide by the study restrictions, and agree to return for the required assesments

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
75 Years

Sex
Both

Target number of participants
100

Key exclusion criteria
1. Currently hospitalized or residing in an in-patient facility during study participation
2. Substance abuse including greater than or equal to 5 units of alcohol per day where 1 unit = ½ pint of beer, 1 glass of wine 4 oz, or 1 oz. of spirits consumed most weeks or in the opinion of the investigator
3. Women who are planning to become pregnant during the course of the study
4. Participation in any clinical trial of an investigational product or device within 30 days of enrollment in this study.
5. Positive screen for drugs of abuse: cocaine, marijuana, PCP, ketamine, opioid or other agent that in the opinion of the investigator is being abused
6. Human immunodeficiency virus (HIV) infection (based on the based on the HIV-1 & HIV-2 antibody screen) or other ongoing infectious disease
7. Pain as a consequence of chemotherapeutic agent for any disease, alcohol- or HIV-induced neuropathic pain.
8. History of separate pain condition, eg, osteoarthritis that is more severe than the neuropathic pain syndrome
9. Lumbar-sacral radiculopathy or failed low back surgery
10. Pain with nerve injury expected to recover within 4 months
11. Complex regional pain syndrome type I
12. Concomitant peripheral neuropathy, paresthesia or dysthesia which cannot be differentiated from neuropathic pain due to other than neuropathic mechanism

Date of first enrolment
15/12/2014

Date of final enrolment
30/12/2015

Locations

Countries of recruitment
United States of America

Study participating centre
433 West Morris Road
Morris
United States of America
06763

Sponsor information

Organisation
Naurex, Inc. (USA)

Sponsor details

1801 Maple Avenue
Suite 4300
Evanston
United States of America
60201
-
ronburch@naurex.com

Sponsor type
Industry

Website
http://www.naurex.com

ROR
https://ror.org/03pfqk412

Funder(s)

Funder type
Industry

Funder Name
Naurex, Inc. (USA)

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