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Clinical trial assessing xenon therapy for panic attack patients

Submission date
10/08/2016

Recruitment status
No longer recruiting

Registration date
14/04/2017

Overall study status
Completed

Last Edited
16/06/2017

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
Anxiety disorders are a group of common disorders in which a person experiences overwhelming and often disabling anxiety. They are very common, and symptoms can range from mild to completely debilitating. Panic disorder is a type of anxiety disorder where the sufferers experiences sudden periods of extreme fear with no prior warming, in the form of a severe panic attack. Xenon is a gas approved in the European Union as an anesthetic and used world-wide in imaging. Research has shown however that the use of xenon is not limited and may be infected in treating certain mental health conditions. The aim of this study is to find out whether xenon can be used as an effective treatment for panic disorder.

Who can participate?
Adults who have been diagnosed with panic disorder.

What does the study involve?
All participants undergo between six and seven treatments. This involves administration of a xenon-oxygen mixture via a face mask, which is inhaled by the participant for 2.5-4 minutes. The first three sessions are carried out daily and from session 4 onwards, every other day. At the start of the study, after each treatment and then after 30 to 180 days, participants complete a number of questionnaires to find out whether the number of panic attacks they have had have reduced and to look at the effect on their mental wellbeing.

What are the possible benefits and risks of participating?
There are no notable benefits or risks involved with participating.

Where is the study run from?
Pirogov Russian National Research Medical University (Russia)

When is the study starting and how long is it expected to run for?
February 2016 to January 2016

Who is funding the study?
Nobilis Therapeutics (USA)

Who is the main contact?
Dr Thomas Ichim

Contact information

Type(s)
Scientific

Contact name
Dr Thomas Ichim

Contact details
Nobilis Therapeutics
9255 Towne Centre Drive, #450
San Diego
United States of America
92121

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
XE001

Study information

Scientific Title
Xenon in the treatment of panic disorder: an open-label study

Study objectives
Administration xenon gas at subanesthetic doses will reduce number of panic attacks in patients with history of panic attack disorder.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Institutional Review Board of the Pirogov Russian National Research Medical University, 13/01/2014, ref: #57689

Study design
Open-label non-randomised study

Primary study design

Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
1. Panic attack disorder
2. Panic attack disorder combined with comorbidity psychiatric conditions

Interventions
All patients undergo administration of a xenon-oxygen mixture via a face mask. Each patient in the study undergoes between 6 and 7 treatments with xenon-oxygen mixture. The first three sessions are carried out daily and from session 4 onwards, every other day.

During the treatments, patients are asked to slowly inhale, holding breath for 5 to 10 seconds, exhale into the loop and after 35-40 seconds exhale outside the contour (to remove CO2) and breathe in the new portion of gas mixture. Xenon inhalation lasts from 2.5 to 4 minutes, and the xenon consumption is capped at 3.0 liters per procedure. The patients are assessed subjectively by the provider, while the vital signs (pulse, blood pressure, oxygen saturation) are continuously monitored. Therapeutic doses used in the mixture of xenon and oxygen in a ratio of xenon to oxygen from 20:80 to 30:70 where the speed of administration is based on the body weight of the patient and baseline spirometry results. As the patients remains fully conscious during the procedure, the administering physician is able to maintain an uninterrupted communication with the patients and to coach them when necessary.

Patients are evaluated after each xenon inhalation and at 30 and 180 days after treatment.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Xenon

Primary outcome measure
Number of panic attacks are assessed through self-reporting throughout the study

Secondary outcome measures
1. Anxiety is measured by the “anxiety” subset of the Hospital Anxiety and Depression Scale (HADS_T) at baseline, 30 and 180 days

2. Severity of disease is assessed by Clinical Global Impression Scale Improvement Subscale (CGI-I) at baseline, 30 and 180 days
3. Symptom changes are quantified by the Zung Self-Rating Anxiety Scale (SAS) at baseline, 30 and 180 days
4. Depression is assessed by the “Depression” subset of the Hospital Anxiety and Depression Scale (HADS_T) at baseline, 30 and 180 days

Overall study start date
11/02/2013

Completion date
14/01/2016

Eligibility

Key inclusion criteria
1. Diagnosis of panic disorder (F41.0) according to ICD-10
2. Age 18-75
3. Willing to sign informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
75 Years

Sex
Both

Target number of participants
90

Key exclusion criteria
1. Known reactions to xenon therapy
2. Organ failure

Date of first enrolment
01/02/2014

Date of final enrolment
11/11/2015

Locations

Countries of recruitment
Russian Federation

Study participating centre
Pirogov Russian National Research Medical University
St. Ostrovityanova 1
Moscow
Russian Federation
117997

Sponsor information

Organisation
Nobilis Therapeutics

Sponsor details
9255 Towne Centre Drive, #450
San Diego
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92121

Sponsor type
Industry

ROR
https://ror.org/03wfcm341

Funder(s)

Funder type
Industry

Funder Name
Nobilis Therapeutics

Results and Publications

Publication and dissemination plan
Planned publication in a peer reviewed journal.

Intention to publish date
31/12/2016

Individual participant data (IPD) sharing plan
The current data sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	13/06/2017		Yes	No