Trial for a new spasticity treatment in MS

What is the title of the trial?
A Phase II Proof of Concept (PoC), Double-Blind, Randomised, Placebo controlled Study to Evaluate the Efficacy, Safety, and Pharmacokinetics of VSN16R for the Treatment of Spasticity in Subjects with Multiple Sclerosis.

What phase is this trial?
Phase II.

What is the trial design?
Randomised double blind placebo controlled proof of concept trial.

Which institution is responsible for the trial?
UCLH NHS Foundation trust.

What's this trial about?
This trial will be testing a drug called VSN16R in the treatment of MS related spasticity.

The drug will be tested in a proof of concept trial which means that the drug being tested has shown promise in the lab and phase I trials already so can now be tested to see if it is effective and safe in people with MS.

How will this help people affected by MS?
Spasticity (muscle stiffness) is a common symptom of MS and the oral treatments currently used to manage have a number of side effects, one of which being sedation.

If this trial shows VSN16R to be effective this could lead to a new treatment for spasticity without the side effects current treatments cause.

What will participants be asked to do?
The trial will last 11 weeks. Each participant will attend a screening visit to ensure eligible and willing to take part. After this, other treatments for spasticity will be withdrawn and they will return for a baseline study visit no less than 10 days after medications are withdrawn.

For five days participants will visit the research unit to be assessed and then administered either the drug or a control treatment. After one week without any treatment, they will then return on a once weekly basis for a three week period during which they will take either the drug or a control treatment twice daily. There will then be two weeks without any treatment before final assessment and the trial ends.

Assessment includes physical examination to assess spasticity, completion of an electronic diary on a daily basis at home as well as ECGs, blood and urine tests.
Who can take part?
Anyone who fits the following criteria can take part in the study:

- Has a confirmed MS diagnosis and spasticity related to MS
- Between age 18-70
- Experiences the minimum level of spasticity met on examination when reviewed
- Able to walk 20 metres with an aid if required
- Not on treatment for spasticity or would be willing to stop current treatment
- Able to attend the research facility 5 days in a row and then on a once weekly basis for 6 weeks
- Has no other significant conditions or psychiatric problems
- Not currently pregnant (planning pregnancy) or breastfeeding
- Has no history drug misuse.

Who is conducting the research?
Dr Rachel Farrell is the Chief Investigator on the study at UCLH NHS Foundation trust (National Hospital for Neurology and Neurosurgery) rachel.farrell@uclh.nhs.uk. Dr Clarence Liu Clarence.liu@bartshealth.nhs.uk is the principal investigator at Barts Health NHS Foundation Trust.

The study is sponsored by Canbex therapeutics Ltd, a small pharmaceutical company established by UCL scientists.

When can I take part in this trial?
September 2015 - September 2016.

Where is this research taking place?
The main site for this trial is the UCLH foundation trust at National Hospital for Neurology and Neurosurgery and Barts health, Royal London Hospital.

Other sites in Sheffield, Liverpool and London will also become active in early 2016.

Who has reviewed this trial?
This study has been reviewed by the NRES London and Surrey borders with ethical approval awarded on 15th January 2015.

Interested?
If you would like more information about taking part in this trial please print the trial information sheet and discuss this with your doctor, MS nurse or neurologist.

Please note that enquiring about participation does not commit you in any way.