Trial for a new spasticity treatment in MS

What phase is this trial?
Phase 2

What is the trial design?
This is a proof of concept trial where participants will be randomised to either take VSN16R or a control treatment. Neither you nor the researchers running the trial will know which group you have been assigned to.

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. This 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 After this, other treatments for spasticity will be withdrawn and they will return for a baseline study visit no less than 10 days after medications are withdrawn.

Participants 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?
We are currently recruiting

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. We are also recruiting at trials sites in Sheffield and Liverpool.

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.