ISRCTN26193242 https://doi.org/10.1186/ISRCTN26193242

A multicentre, multinational prospective observational imaging biomarker study in early stage Huntingtons disease (HD) patients to assess imaging techniques and parameters able to support efficacy studies with SEN0014196 in HD patients during Phase II and III studies

Submission date
07/06/2011

Registration date
07/06/2011

Last Edited
29/03/2017

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Nervous System Diseases

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT01485952

Clinical Trials Information System (CTIS)
2010-021563-32

Protocol serial number
9944

Study information

Scientific Title
A multicentre, multinational prospective observational imaging biomarker study in early stage Huntingtons disease (HD) patients to assess imaging techniques and parameters able to support efficacy studies with SEN0014196 in HD patients during Phase II and III studies

Acronym
SEN0014196

Study objectives
The study is an exploratory, multicentre, randomised and double blind placebo controlled, parallel group design at two dose levels with once daily administration over two weeks in clinical stages I-II of Huntingtons disease (HD) patients.

SEN0014196 is an investigational drug previously tested on healthy volunteers and will be tested for the first time on patients with HD. Previous studies in healthy volunteers have shown the drug to be safe and well tolerated. This study is expected to provide further information on how the compound works in humans and help further clinical development of SEN0014196. The study will be conducted at two different dose levels (10mg or 100mg of SEN0014196 given orally once daily) and there will also be a placebo arm. The study will assess what the drug does to the body (Pharmacodynamic effect) and what the body does to the drug (Pharmacokinetics). To do this repeated blood samples will be taken for the duration of the study. Safety assessments will also be conducted including ECGs, Blood Pressure, Pulse, Body Temperature, Laboratory Safety tests and a Physical Exam.

The total duration of the study is 28 days (14 days on treatment plus a 14 day Follow up Period), excluding the Screening period. 60 patients (males & females aged 18 to 70) with early stage HD will be involved in this study which will be conducted across 6 sites in the EU.

Ethics approval required
Old ethics approval format

Ethics approval(s)
10/H0803/169; First MREC approval date 07/02/2011

Primary study design
Interventional

Study design
Randomised; Interventional; Design type: Treatment

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Topic: Dementias and Neurodegenerative Diseases Research Network; Subtopic: Huntingtons Disease; Disease: Huntington's disease

Interventions
Repeated blood sampling, pharmacokinetic and pharmacodynamic measurements relating to study drug; study drug/placebo, safety and efficacy study of drug versus placebo; Study Entry : Single Randomisation only

Intervention Type
Other

Phase
Phase I/II

Primary outcome(s)
Pharmacokinetic & pharmacodynamic blood sample analysis; Timepoint(s): various depending on study visit

Key secondary outcome(s)
Acute phenotypical effects; Timepoint(s): cognitive, motor, functional, behavioural and quality of life measures

Completion date
11/11/2011

Eligibility

Key inclusion criteria
1. Patients with early Huntingtons Disease (aged 18 to 70 years), i.e. genetically confirmed (CAG repeat length = 36) HD, motor signs of HD (motor score of the Unified Huntington's Disease Rating Scale [UHDRS] > 5) and a Total Functional Capacity (TFC) of = 7
2. All patients will have a body weight greater than 50kg
3. Female subjects must be surgically sterile or postmenopausal (defined as at least two years post cessation of menses and/or follicular stimulating hormone >18 mIU/mL and serum oestradiol <110 pmol/L), no spontaneous menstruation for at least one year before the first dose, nonlactating and have a negative serum pregnancy test
[Note: For postmenopausal females treated with estrogen replacement therapy, folloicle stimulating hormones (FSH) levels are artificially lowered < 40 IU/L. Estradiol and Luteinizing hormone (LH) measurements need to be performed to confirm reason for low FSH value. Hormone replacement therapy (HRT) is acceptable, provided the above criteria are respected].
4. All subjects must be capable of providing written informed consent
5. Subjects must have no clinically significant and relevant history that could affect the conduct of the study and evaluation of the data, as ascertained by the Investigator through detailed medical history and screening assessments
6. Male subjects participating in the trial and their female partners must agree to use a highly effective method of contraception from the time of taking the first dose of the study drug until three months after taking the last dose. This must include a condom or other barrier method (i.e. a diaphragm or cervical/vault cap), with spermicidal cream/gel plus one extra method (i.e. established use of oral, injected or implanted hormonal contraception or IUD or Coil). If the

female partner is already pregnant, use of condoms is mandatory during sexual intercourse from the time of taking the first dose of study drug until three months after taking the last dose of study drug.
Target Gender: Male & Female; Upper Age Limit 70 years ; Lower Age Limit 18 years

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. Participation in a study of an investigational drug within 30 days of the baseline visit
2. Subjects with presence of psychosis and/or confusional states
3. Subjects with clinically significant laboratory or electrocardiogram (ECG) abnormalities at screening
4. Subjects with clinically relevant haematological, hepatic, cardiac or renal disease
5. A medical history of infection with Human immunodeficiency virus, Hepatitis C and/or Hepatitis B
6. Any relevant condition, behaviour, laboratory value or concomitant medication which, in the opinion of the Investigator, makes the subject unsuitable for entry into the study
7. Subjects who have previously received histone deacetylase inhibitors e.g. vorinostat (Zolinza®) or have participated in a clinical trial using a histone deacetylase inhibitor
8. A history of malignancy of any type within 2 years prior to screening. A history of surgically excised nonmelanoma skin cancers is permitted
9. Subjects with a significant history of drug allergy as determined by the Investigator
10. Subjects who consume more than 28 units (males) or more than 21 units (females) of alcohol per week or who have a significant history of alcoholism or drug/ chemical abuse as determined by the Investigator (one unit of alcohol equals 285 mL of beer or lager, one glass [125 mL] of wine, or 25 mL of spirits)

Date of first enrolment
11/04/2011

Date of final enrolment
11/11/2011

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University College London
London
United Kingdom
WC1E 6BT

Sponsor information

Organisation
Siena Biotech (Italy)

ROR
https://ror.org/02ka1d450

Funder(s)

Funder type
Government

Funder Name
Seventh Framework Programme

Alternative Name(s)
Seventh framework programme of the European Community for research and technological development and demonstration activities (2007-2013), FP7

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/03/2015		Yes	No
HRA research summary			28/06/2023	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes