

A randomised, double-blind, placebo-controlled, cross-over pilot study using nabilone for symptomatic relief in patients with Huntington's disease

Submission date 07/09/2005	Recruitment status No longer recruiting	☐ Prospectively registered
Registration date 13/09/2005	Overall study status Completed	☐ Protocol
Last Edited 01/02/2013	Condition category Nervous System Diseases	☐ Statistical analysis plan
		☒ 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

Protocol serial number

Sponsor 583; Eudract test 0000632-21

Study information

Scientific Title

Study objectives

That nabilone will have a beneficial effect on movement and psychiatric symptoms in patients with Huntington's disease

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised double blind placebo controlled crossover group trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Huntington's disease

Interventions

Nabilone or placebo for 5 weeks, 5 week washout period cross over to nabilone or placebo for 5 weeks

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Nabilone

Primary outcome(s)

Motor symptoms rated using the motor scale from the UHDRS

Key secondary outcome(s)

Psychiatric symptoms rated using the behavioural assessment of the UHDRS and the NPI

Completion date

01/12/2006

Eligibility

Key inclusion criteria

Competent patients with a clinical diagnosis of Huntington's disease over 18

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

1. Under 18
2. Known allergy to cannabinoids
3. Liver dysfunction
4. Personal or family history of psychosis
5. Heart disease or hypertension
6. Pregnant or lactating

Date of first enrolment

01/09/2005

Date of final enrolment

01/12/2006

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Queen Elizabeth Psychiatric Hospital

Birmingham

United Kingdom

B15 2QZ

Sponsor information

Organisation

Birmingham and Solihull Mental Health Trust (UK)

ROR

<https://ror.org/00cjeg736>

Funder(s)**Funder type**

Industry

Funder Name

Cambridge Laboratories (UK) - hold the European marketing rights for nabilone

Results and Publications**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	15/11/2009		Yes	No