

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	<input type="checkbox"/> Prospectively registered
Registration date 13/09/2005	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 01/02/2013	Condition category Nervous System Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Hugh Rickards

Contact details
Queen Elizabeth Psychiatric Hospital
Vincent Drive
Edgbaston
Birmingham
United Kingdom
B15 2QZ
+44 (0)121 678 2019
hugh.rickards@bsmht.nhs.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

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 measure

Motor symptoms rated using the motor scale from the UHDRS

Secondary outcome measures

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

Overall study start date

01/09/2005

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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

40

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

England

United Kingdom

Study participating centre

Queen Elizabeth Psychiatric Hospital

Birmingham

United Kingdom

B15 2QZ

Sponsor information**Organisation**

Birmingham and Solihull Mental Health Trust (UK)

Sponsor details

Uffculme Centre

Queensbridge Road

Moseley

Birmingham

England

United Kingdom

B13 8QY

+44 (0)121 678 2731

theresa.morton@bsmht.nhs.uk

Sponsor type

Hospital/treatment centre

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

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

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