ISRCTN16782845 https://doi.org/10.1186/ISRCTN16782845

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

Registration date
13/09/2005

Overall study status
Completed

Last Edited
01/02/2013

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

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
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England
United Kingdom
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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