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

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

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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 Pirmingham

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