MUltiple Sclerosis and Extract of Cannabis (MUSEC): a randomised, double-blind, placebo-controlled phase III trial to determine the efficacy and safety of a standardised oral extract of Cannabis sativa for the symptomatic relief of muscle stiffness and pain in Multiple Sclerosis (MS)

Submission date	<b>Recruitment status</b> No longer recruiting	Prospectively registered		
10/10/2007		☐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
17/10/2007	Completed	[X] Results		
Last Edited	Condition category	Individual participant data		
03/02/2015	Nervous System Diseases			

## Plain English summary of protocol

Not provided at time of registration

## Study website

http://www.msmusecstudy.com

# Contact information

## Type(s)

Scientific

#### Contact name

Prof John Zajicek

#### Contact details

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# Additional identifiers

**EudraCT/CTIS** number

**IRAS** number

ClinicalTrials.gov number NCT00552604

Secondary identifying numbers '25-01

# Study information

#### Scientific Title

MUltiple Sclerosis and Extract of Cannabis (MUSEC): a randomised, double-blind, placebocontrolled phase III trial to determine the efficacy and safety of a standardised oral extract of Cannabis sativa for the symptomatic relief of muscle stiffness and pain in Multiple Sclerosis (MS)

## Acronym

**MUSEC** 

## **Study objectives**

To determine the efficacy and safety of a standardised extract of Cannabis sativa given orally 2 times daily as compared to placebo for the relief of muscle stiffness and pain in multiple sclerosis for a period of 12 weeks.

## Ethics approval required

Old ethics approval format

# Ethics approval(s)

Multi-centre Research Ethics Committee For Scotland, 31/01/2006, ref: 05/MRE10/97

## Study design

Multi-centre randomised double-blind placebo-controlled two-arm parallel study

# Primary study design

Interventional

# Secondary study design

Randomised controlled trial

## Study setting(s)

Not specified

# Study type(s)

**Treatment** 

## Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

## Health condition(s) or problem(s) studied

Multiple sclerosis

#### **Interventions**

- 1. Cannabis extract (delta-9-tetrahydrocannabinol [THC] 2.5 mg, Cannabidiol [CBD] 1.25 mg per capsule) start dose 5 mg THC per day, followed by individual dose titration with increase of 5 mg THC every 3 days, maximal dose 25 mg, administered orally as 2 equal doses per day based on tolerability
- 2. Matched placebo

There is no follow up for the trial (total duration of trial is 12 weeks from randomisation).

## Added 12/09/2008:

Recruitment for the MUSEC Study has now been completed. Last patient randomised was 04/09 /2008. The Last Patient Last Visit is expected in November 2008.

## Intervention Type

Drug

#### Phase

Phase III

## Drug/device/biological/vaccine name(s)

Cannabis sativa extract

#### Primary outcome measure

Change in muscle stiffness: 11-point numerical Likert scale, measured at 12 weeks.

#### Secondary outcome measures

- 1. Change in pain: 11-point numerical Likert scale, measured at 12 weeks
- 2. Amount of muscle stiffness: 11-point numerical Likert scale, measured at 2, 4, 8 and 12 weeks
- 3. Amount of pain: 11-point numerical Likert scale, measured at 2, 4, 8 and 12 weeks
- 4. Change/amount of spasms: 11-point numerical Likert scales, measured at 2, 4, 8 and 12 weeks
- 5. Change/amount of sleep disturbance: 11-point numerical Likert scales, measured at 2, 4, 8 and 12 weeks
- 6. Disease-specific Quality of Life: Multiple Sclerosis Spasticity Scale (MSSS)-88 and Multiple Sclerosis Impact Scale (MSIS)-29, measured at 4 and 12 weeks
- 7. Patient-rated walking ability: Multiple Sclerosis Walking Scale (MSWS)-12, measured at 4 and 12 weeks

## Overall study start date

20/06/2006

#### Completion date

30/06/2008

# **Eligibility**

#### Key inclusion criteria

- 1. Diagnosis of MS according to McDonald criteria
- 2. Current muscle stiffness greater than or equal to 4 on a 11-point categorical rating scale
- 3. On-going troublesome muscle stiffness for at least 3 months before enrolling in the trial
- 4. Stable disease for the previous 6 months in the opinion of the treating physician
- 5. Antispasticity medication and physiotherapy stabilised for the last 30 days
- 6. Patients may be ambulatory or not
- 7. Age 18 64 years

## Participant type(s)

**Patient** 

## Age group

Adult

## Lower age limit

18 Years

## Upper age limit

64 Years

#### Sex

Both

## Target number of participants

400

#### Kev exclusion criteria

- 1. Immunosuppressants which may affect spasticity (including corticosteroids and interferon but excluding azathioprine) taken currently or in previous 30 days
- 2. Open/infected pressure sores or other source of chronic infection
- 3. Significant fixed tendon contractures
- 4. Cannabinoids taken currently or in previous 30 days
- 5. Positive qualitative urinary test on cannabinoids at screening visit
- 6. Laboratory parameters outside the following limits:
- 6.1. Creatinine greater than 3 x upper limit of normal
- 6.2. Bilirubin greater than 3 x upper limit of normal
- 6.3. Transaminases greater than 5 x upper limit of normal

#### Date of first enrolment

20/06/2006

#### Date of final enrolment

30/06/2008

# Locations

#### Countries of recruitment

## England

**United Kingdom** 

Study participating centre Peninsula Medical School Plymouth United Kingdom PL6 8BX

# Sponsor information

## Organisation

Institute for Clinical Research (Institut fur klinische Forschung) (Germany)

## Sponsor details

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### Sponsor type

Research organisation

#### Website

http://www.ikf-berlin.de

# Funder(s)

# Funder type

Industry

#### Funder Name

Weleda AG (Germany)

# **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	01/11/2012		Yes	No