

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 10/10/2007	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 17/10/2007	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 03/02/2015	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

Not provided at time of registration

Study website

<http://www.msmusecstudy.com>

Contact information

Type(s)

Scientific

Contact name

Prof John Zajicek

Contact details

Peninsula Medical School
ITTC Building 1
Tamar Science Park
1 Davy Road
Plymouth
United Kingdom
PL6 8BX

+44 (0)1752 315 250
John.ZAJICEK@phnt.swest.nhs.uk

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, 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)

Acronym

MUSEC

Study hypothesis

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

Condition

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

Overall study end date

30/06/2008

Eligibility

Participant 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

Participant 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

Recruitment start date

20/06/2006

Recruitment end date

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 für klinische Forschung) (Germany)

Sponsor details

Hardenbergstr. 19
Berlin
Germany
D-10623
+49 (0)30 315 744 71
martin.schnelle@ikf-berlin.de

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