ISRCTN42223114 https://doi.org/10.1186/ISRCTN42223114

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

Registration date
17/10/2007

Overall study status
Completed

Last Edited
03/02/2015

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

Study website
http://www.msmusecstudy.com

Contact information

Type(s)
Scientific

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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, 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 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

Key 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
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Sponsor information

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

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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