

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	☐ Prospectively registered
Registration date 17/10/2007	Overall study status Completed	☐ Protocol
Last Edited 03/02/2015	Condition category Nervous System Diseases	☐ Statistical analysis plan
		☒ 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

ClinicalTrials.gov (NCT)

NCT00552604

Protocol serial number

'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

Primary study design

Interventional

Study design

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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Upper age limit

64 Years

Sex

All

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**

United Kingdom

England

Study participating centre

Peninsula Medical School

Plymouth

United Kingdom

PL6 8BX

Sponsor information**Organisation**

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

Funder(s)

Funder type

Industry

Funder Name

Weleda AG (Germany)

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	01/11/2012		Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes