Clinical trial results:
Pilot Study of Homeopathic Treatment of Fibromyalgia Syndrome (HOFS)

Summary

EudraCT number	2005-004511-29
Trial protocol	GB
Global end of trial date	07 July 2007

Results information

Result version number	v1 (current)
This version publication date	08 October 2021
First version publication date	08 October 2021

Trial information

Trial identification

Sponsor protocol code	resgov/8nov05/01

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	-
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Barnsley Hospital NHS Foundation Trust
Sponsor organisation address	Research and Development, Block 14, Barnsley Hospital, Gawber Road, Barnsley, United Kingdom, S75 2EP
Public contact	Barnsley Hospital NHS Foundation Trust, Barnsley Hospital NHS Foundation Trust, barnsley.research@nhs.net
Scientific contact	Barnsley Hospital NHS Foundation Trust, Barnsley Hospital NHS Foundation Trust, barnsley.research@nhs.net

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	30 April 2009
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	07 July 2007
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To evaluate the comparative effectiveness of a homeopathy intervention relative to usual care

Protection of trial subjects:

No specific measures were put in place

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 January 2006
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	United Kingdom: 47
Worldwide total number of subjects	47
EEA total number of subjects	47

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	47
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Diagnosis of FMS (ACR criteria)

Period 1

Period 1 title	Overall Trial (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	Usual Care

Arm description: -

Arm type	No intervention

No investigational medicinal product assigned in this arm

Arm title	Usual care plus adjunctive care by a homeopath

Arm description: -

Arm type	Intervention
Investigational medicinal product name	individually tailored homeopathic medicines
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

The homeopath care group received usual care plus an initial one hour in depth interview followed by up to four 30 min in depth interviews (4–6 weeks apart) with individually tailored homeopathic medicines prescribed at each interview.

Number of subjects in period 1	Usual Care	Usual care plus adjunctive care by a homeopath
Started	24	23
Completed	16	20
Not completed	8	3
Consent withdrawn by subject	-	2
Emigrated	-	1
Lost to follow-up	8	-

Baseline characteristics

End points

End points reporting groups

Reporting group title	Usual Care
Reporting group description: -	
Reporting group title	Usual care plus adjunctive care by a homeopath
Reporting group description: -	

Primary: Difference in the Fibromyalgia Impact Questionnaire (FIQ) total scores

End point title	Difference in the Fibromyalgia Impact Questionnaire (FIQ) total scores
End point description:	
End point type	Primary
End point timeframe:	
22 weeks	

End point values	Usual Care	Usual care plus adjunctive care by a homeopath		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	16	20		
Units: Fibromyalgia Impact Questionnaire (FIQ)				
number (not applicable)	16	20		

Statistical analyses

Statistical analysis title	FIQ score
Comparison groups	Usual Care v Usual care plus adjunctive care by a homeopath
Number of subjects included in analysis	36
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.82
Method	Mixed models analysis

Adverse events

Adverse events information[1]	
Timeframe for reporting adverse events: 24 hours for SAEs	
Assessment type	Non-systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	12

Frequency threshold for reporting non-serious adverse events: 5 %

Notes:

[1] - There are no non-serious adverse events recorded for these results. It is expected that there will be at least one non-serious adverse event reported.
Justification: There were no reported adverse events

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported

Online references

http://www.ncbi.nlm.nih.gov/pubmed/19358959