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A multi-centre, double-blind, placebo-controlled, multiple-dose crossover proof of concept study to compare the efficacy of mefenamic acid administered vaginally and orally in healthy menstruating women with primary dysmenorrhoea requiring analgesia

Submission date	Recruitment status	[_] Prospectively registered
22/08/2007	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
04/10/2007	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
10/07/2017	Urological and Genital Diseases	[_] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr David Bell

Contact details
Bio-Kinetic Europe Limited
14 Great Victoria Street
Belfast
Ireland
BT2 7BA
+ 44 (0)28 9081 8381
david@biokineticeurope.com

Additional identifiers

Protocol serial number
PSD508-DYS-001

Study information

Scientific Title
A multi-centre, double-blind, placebo-controlled, multiple-dose crossover proof of concept study to compare the efficacy of mefenamic acid administered vaginally and orally in healthy menstruating women with primary dysmenorrhoea requiring analgesia

Study objectives
Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) are commonly prescribed for dysmenorrhoea, and are very effective. However, all oral NSAIDs can cause gastrointestinal upset. This study aims to assess a direct vaginal delivery system for a well established NSAID in patients with primary dysmenorrhoea. Potential advantages for intra-vaginal delivery of NSAIDs are higher local concentrations of active agent and a reduced incidence of gastrointestinal side effects.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Office for Research Ethics Committees Northern Ireland (ORECNI), 25/05/2007, ref: 07/NIR03/42

Study design
Multi-centre double-blind placebo-controlled multiple-dose crossover study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Primary dysmenorrhoea

Interventions
Subjects will attend a total of four study visits over three menstrual periods:
1. A screening visit (Visit 1) before the first menstrual bleed
2. A treatment period visit (Visit 2) prior to the second menstrual bleed
3. A treatment period visit (Visit 3) prior to the third menstrual bleed
4. A follow-up visit (Visit 4) after treatment of the third menstrual bleed

Dosage:
Oral capsules = 2 x 250 mg
Intra-vaginal NSAID applied to tampons = 1 x 80 mg

Tampons will be used to dose up to six times during a single 24-hour period. Tampons will remain in situ for four hours, except overnight when a tampon may be worn for eight hours if desired. Capsules for oral administration will be taken three times daily (at intervals of eight hours) for 24 hours.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Mefenamic acid

Primary outcome(s)
Menstrual-related pain intensity, recorded in a diary at baseline and a variety of timepoints over 24 hours

Key secondary outcome(s))
Safety and tolerability of PSD508, measured over a period of 24 hours

Completion date
29/04/2008

Eligibility

Key inclusion criteria
1. Healthy menstruating female with a history of primary dysmenorrhoea
2. Menstrual-related pain with cramping for which she requires the use of analgesics during each cycle
3. Regular menstrual cycles
4. Routinely uses intra-vaginal tampons and is able to use tampons without an applicator
5. Aged 18 to 40 years inclusive
6. No clinically significant medical history and normal clinical examination other than the underlying pathology requiring treatment, in the opinion of the Investigator
7. Able to understand and complete the rating scales
8. Provided written informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
Female

Key exclusion criteria
A subject will be excluded from study participation if she meets any of the following criteria:
1. Has a history of, or known, hypersensitivity to mefenamic acid
2. Has a history of reactions such as asthma, urticaria, or allergic type reactions to other NSAIDs

3. Has received another investigational product within three months prior to screening
4. Is unwilling to avoid the use of any:
4.1. Opiate* within 24 hours
4.2. NSAID within 6 hours, or
4.3. Paracetamol within 4 hours, of starting study medication
5. Is pregnant, lactating, or is planning to become pregnant during the study
6. Is currently receiving or has received any hormonal contraception within the previous three months
7. Does not agree to use suitable non-hormonal contraception for the duration of the study
8. Has a history of Toxic Shock Syndrome (TSS)
9. Has a current untreated Sexually Transmitted Disease (STD) that could interfere with the study
10. Has, or has had, ulcerative, vesicular or papillomatous lesions of the cervix, vagina or genital area
11. Is known not to respond to mefenamic acid
12. Has signs or symptoms that contraindicate the administration of mefenamic acid
13. Has unresolved alcohol or drug abuse
14. Has severe menorrhagia which, in the opinion of the investigator, could interfere with the study
15. Is using complementary therapy, such as evening primrose oil, for the treatment of symptoms
16. Has any other condition which, in the opinion of the investigator, may interfere with the study

*Up to 16 mg codeine per dose (i.e., 2 co-codamol 8/500 mg tablets) is acceptable

Date of first enrolment
03/10/2007

Date of final enrolment
29/04/2008

Locations

Countries of recruitment
United Kingdom

Ireland

Study participating centre
Bio-Kinetic Europe Limited
Belfast
Ireland
BT2 7BA

Sponsor information

Organisation

Plethora Solutions Limited (UK)

ROR
https://ror.org/02y9vw172

Funder(s)

Funder type
Industry

Funder Name
Plethora Solutions Limited (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration