# A multi-centre, double-blind, placebocontrolled, 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	<ul><li>Record updated in last year</li></ul>

# **Plain English summary of protocol**Not provided at time of registration

# Contact information

# Type(s)

Scientific

#### Contact name

Dr David Bell

#### Contact details

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# 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 =  $2 \times 250 \text{ mg}$ 

Intra-vaginal NSAID applied to tampons =  $1 \times 80 \text{ mg}$ 

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

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

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

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

## **Study outputs**

Output type Details Date created Date added Peer reviewed? Patient-facing?

Participant information sheet Participant information sheet 11/11/2025 11/11/2025 No Yes