

Dysmenorrhoea Efficacy Study: fixed dose combination tablets of ibuprofen and acetaminophen for primary dysmenorrhoea

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Registration date 20/10/2009	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 30/03/2011	Condition category Urological and Genital Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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

Clinical Trials Information System (CTIS)
2008-006762-29

Protocol serial number
NL0804

Study information

Scientific Title

A double-blind, randomised crossover, single dose, single centre, study examining the analgesic efficacy and tolerability of fixed-dose combinations of ibuprofen 200 mg and acetaminophen 500 mg, ibuprofen 400 mg and acetaminophen 1,000 mg and placebo in primary dysmenorrhoea

Acronym

Dysmenorrhoea Efficacy Study

Study objectives

The primary objective of the study is to assess the efficacy of fixed dose combination tablets of 200 mg ibuprofen plus 500 mg acetaminophen, administered as one or two tablets (two tablets equivalent to 400 mg ibuprofen plus 1,000 mg acetaminophen) in comparison to placebo among patients experiencing moderate to severe pain due to primary dysmenorrhoea, in terms of total analgesic effect.

Ethics approval required

Old ethics approval format

Ethics approval(s)

South East Wales Ethics Committee panel B approved on the 14 January 2009 (ref: 09/WSE02/7)

Study design

Double-blind randomised crossover single dose single centre study

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Primary dysmenorrhoea

Interventions

Fixed dose combination tablets of 200 mg ibuprofen plus 500 mg acetaminophen, administered as one or two tablets (two tablets equivalent to 400 mg ibuprofen plus 1,000 mg acetaminophen) in comparison to placebo.

The treatments were single doses of the test medicine taken on three menstrual cycles if the pain was of sufficient intensity to need treatment. The duration of the follow-up was for up to five days after the last dose of treatment.

Intervention Type

Drug

Phase

Phase II/III

Drug/device/biological/vaccine name(s)

Ibuprofen, acetaminophen

Primary outcome(s)

The primary analgesic efficacy endpoint will be the total pain relief over 6 hours post-dose

Key secondary outcome(s)

Total pain relief over 2 and 4 hours post-dose

Completion date

30/06/2009

Eligibility

Key inclusion criteria

1. Female patients aged greater than or equal to 18 years
2. Primary diagnosis of primary dysmenorrhoea, with moderate-severe cramping pain in at least 4 of the previous 6 months
3. Responded to any study-specific advertising, or have indicated to staff that they wish to participate in a dysmenorrhoea trial
4. Have given written informed consent

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

Female

Key exclusion criteria

1. A history of significant disease deemed by the investigator to render the subject unsuitable for inclusion
2. Any significant ongoing painful condition other than that associated with primary dysmenorrhoea
3. Any ongoing condition that may interfere with the absorption, distribution, metabolism, or excretion of the study medication
4. A history of peptic ulcer, duodenal ulcer, gastrointestinal bleeding
5. A history of frequent dyspepsia, heartburn or indigestion
6. A history of psychotic illness, attempted suicide, or neurosis
7. A positive history of drug or alcohol abuse within the past year
8. Those taking any concomitant medications that might confound assessments of pain relief, such as psychotropic drugs, antidepressants, sedativehypnotics taken within five times of their

elimination half lives. Selective serotonin reuptake inhibitors (SSRIs) and serotonin and noradrenaline reuptake inhibitors (SNRIs) are permitted if the subject has been on a stable dose for at least four weeks prior to Visit 1 (screening) and remain on this dose throughout the study.

9. Woman of childbearing potential, who are pregnant or lactating, seeking pregnancy or failing to take adequate contraceptive precautions, (i.e. an oral or injectable contraceptive, an approved hormonal implant or topical patch, an intrauterine device, abstinence [should the subject become sexually active, she must agree to use a double barrier method] or condoms /diaphragm and spermicide). A woman of childbearing potential is defined as any female who is less than 2 years post-menopausal or has not undergone a hysterectomy or surgical sterilisation, e.g. bilateral tubal ligation, bilateral ovariectomy (oophorectomy).

10. A history of inflammatory bowel disease (e.g., Crohn's disease or ulcerative colitis), a chronic or acute renal or hepatic disorder, a significant coagulation defect, or any previous history of allergy or known intolerance to any of the drugs or formulation constituents which, in the Investigator's opinion, might preclude use of a non-steroidal anti-inflammatory drug [NSAID], including aspirin sensitive asthma or a previous allergic response to a NSAID, including bronchospasm, urticaria, angioedema and rhinitis)

11. Those previously randomised into this study

12. Subjects who have received any analgesic, anti-inflammatory, antispasmodic or other therapy for dysmenorrhoea within 6 hours of taking the study medication

13. Those who have participated in a clinical trial in the previous 30 days weeks are calculated from time of last dosing in the prior trial to time of anticipated dosing in this trial

14. Those suffering with anaemia (blood test at screening visit)

15. Those unable, in the opinion of the investigator, to comply fully with the study requirements

Date of first enrolment

02/01/2009

Date of final enrolment

30/06/2009

Locations

Countries of recruitment

United Kingdom

Wales

Study participating centre

Common Cold Centre and Healthcare Clinical Trials Unit

Cardiff

United Kingdom

CF10 3AX

Sponsor information

Organisation

Reckitt Benckiser Healthcare (UK)

ROR

<https://ror.org/01g87hr29>

Funder(s)

Funder type

Industry

Funder Name

Reckitt Benckiser Healthcare (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?
Results article	results	01/11/2010		Yes	No
HRA research summary			28/06/2023	No	No