ISRCTN42521357 https://doi.org/10.1186/ISRCTN42521357

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

Submission date	Recruitment status	[_] Prospectively registered
07/10/2009	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
20/10/2009	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
30/03/2011	Urological and Genital Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
2008-006762-29

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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

Secondary outcome measures
Total pain relief over 2 and 4 hours post-dose

Overall study start date
02/01/2009

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

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
85

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 fives 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 an non-steroidal anti-inflammatory drug [NSAID], including aspirin sensitive asthma or a previous allergic respresponse 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)

Sponsor details
c/o A Holbrook
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United Kingdom
HU8 7DS

Sponsor type
Industry

Website
http://www.reckittbenckiser.com/home

ROR
https://ror.org/01g87hr29

Funder(s)

Funder type
Industry

Funder Name
Reckitt Benckiser Healthcare (UK)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

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