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Comparison of Advil® and Tylenol® Extra Strength, separately and in combination, to alleviate postoperative dental pain

Submission date	Recruitment status	[_] Prospectively registered
09/06/2010	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
24/06/2010	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
31/10/2019	Oral Health	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
NL0408

Study information

Scientific Title

Comparing the analgesic efficacy of Advil® and Tylenol® Extra Strength, separately and in combination, in patients experiencing postoperative dental pain: A double blind, randomised, placebo controlled, parallel group trial with modified factorial design

Study objectives
The objective of this study was to compare the analgesic efficacy of Advil® tablets (200 or 400 mg ibuprofen) given concurrently with Tylenol® Extra Strength (ES) caplets (500 or 1000 mg acetaminophen [paracetamol]) to:
1) Advil tablets (400mg ibuprofen) alone;
2) Tylenol ES caplets (1000mg acetaminophen) alone;
3) Placebo
among subjects experiencing moderate to severe postoperative dental impaction pain. Analgesic efficacy was measured in terms of total effect, peak effect, onset and duration of effect, and subjects overall assessment of the study medication.

A secondary objective was to evaluate the tolerability (adverse event [AE] profile) of the combination of Advil tablets (200 or 400 mg ibuprofen) given concurrently with Tylenol Extra Strength (500 or 1000 acetaminophen) to the individual ingredients and to placebo.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Quorum Review (Seattle, WA) independent institutional review board (IRB) approved on the 8th of October 2004

Study design
Randomised double blind placebo controlled single dose modified factorial design study using the dental impaction pain model

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Dental Pain

Interventions
Subjects were randomly allocated to one of the 5 treatment groups:
1. 400mg Ibuprofen alone
2. 1000mg Acetaminophen alone
3. 400mg Ibuprofen plus 1000mg acetaminophen
4. 200mg Ibuprofen plus 500mg acetaminophen
5. Placebo

Intervention Type
Other

Phase
Phase IV

Primary outcome(s)
Sum of Pain Relief and Pain Intensity Differences from 0-8 hours (SPRID 0-8)

Key secondary outcome(s))
1. Total Pain Relief from 0 to 8 hours (TOTPAR 0-8)
2. Sum of the Pain Intensity Differences from 0 to 8 hours (SPID 0-8)
3. Sum of the Pain Intensity Differences on the VAS scale from 0 to 8 hours (SPID VAS 0-8)
4. TOTPAR, SPID, SPRID, and SPID VAS from 0 to 4 hours (0-4) and 0 to 6 hours (0-6)
5. Individual pain relief (PR) readings at each time point from 15 minutes to 8 hours
6. Peak PR recorded during the 8-hour evaluation period
7. Individual PID at each time point from 15 minutes to 8 hours
8. Individual PID for the VAS scale (PID VAS) at each time point from 15 minutes to 8 hours
9. Peak PID and peak PID VAS recorded during the 8-hour evaluation period
10. First time at which the PID was at least 1
11. Time to first perceptible pain relief
12. Time to first confirmed perceptible pain relief
13. Time to first meaningful pain relief
14. Time to use of rescue medication
15. Time to pain half gone
16. Subjects overall (global) assessment

Completion date
15/02/2005

Eligibility

Key inclusion criteria
1. Age: between the ages of 16 and 40 years of age
2. Sex: either male or female
3. Primary diagnosis: At least three impacted third molars (two of which must have been mandibular impacted molars) indicated for removal. Both mandibular impactions must have required bone removal, and there must have been a total score of 9 or greater on the impaction grading scale for the three or four impacted third molar
4. Baseline Pain Intensity: were experiencing postoperative pain of at least moderate based on the pain intensity categorical rating scale and a pain intensity VAS score of 50mm or greater on the 100mm VAS Scale
5. Consent: gave written informed consent. Subjects who were 16 or 17 years of age also required their parents or legal guardian to provide written informed consent in addition to their written assent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group

Adult

Sex
All

Total final enrolment
234

Key exclusion criteria
1. Had a current history of significant disease deemed by the investigator to render the subject unsuitable for inclusion
2. Had any ongoing painful condition other than that associated with their third molar surgery
3. Had an ongoing condition that may have interfered with the absorption, distribution, metabolism or excretion of the study drug
4. Had a history of allergy (including angioedema, urticaria, bronchospasm and rhinitis) related to the treatment with ibuprofen, acetaminophen, aspirin, other NSAIDs or any other medication used in this study
5. A history of frequent peptic ulcers, duodenal ulcers or GI bleeding
6. A history of frequent dyspepsia, heartburn or indigestion
7. A history of migraine headaches within the past year
8. A history of psychotic illness, attempted suicide or neurosis
9. Those unable to refrain from smoking during their stay in the research centre
10. A positive history of drug or alcohol abuse within the past six months
11. Those who were taking any concomitant medication that might have confounded assessments of pain relief (PAR), such as: psychotropic drugs, antidepressants, sedative-hypnotics (other than those permitted for conscious sedation), or other analgesics taken within five times of their elimination half lives. Selective serotonin reuptake inhibitors (SSRIs) and serotonin noradrenalin reuptake inhibitors (SNRIs) were permitted if the subject had been on a stable dose for at least four weeks prior to visit 1 (screening)
12. Those who were unable, in the opinion of the investigator, to comply fully with the study requirements
13. Those previously randomised into this study
14. Those who had participated in a clinical trial in the previous 12 weeks. Twelve weeks (calculated from the time of last dosing in the prior trial to time of anticipated dosing in this trial)

Date of first enrolment
02/11/2004

Date of final enrolment
15/02/2005

Locations

Countries of recruitment
United States of America

Study participating centre
SCIREX Research Center/ Premier Research Group
Austin

United States of America
TX 78705

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	01/05/2010	31/10/2019	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes