

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

Submission date 09/06/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 24/06/2010	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 31/10/2019	Condition category Oral Health	<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

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