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Comparative effect of intraoperative propacetamol administration versus placebo on morphine consumption after elective reduction mammoplasty

Submission date 27/08/2004	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 27/08/2004	**Overall study status** Completed	
Last Edited 13/08/2009	**Condition category** Surgery	

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

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Study objectives
Postoperative administration of paracetamol has been shown to decrease pain with a morphine sparing effect. However, the effect of propacetamol administered intra-operatively on post-operative pain and early postoperative morphine consumption has not been clearly evaluated. In order to evaluate the effectiveness of analgesic protocols in the management of post-operative pain, a standardized anesthesia protocol without long-acting opioids is crucial. Thus, for ethical reasons, the surgical procedure under general anesthesia with remifentanil as the only intraoperative analgesic must be associated with a moderate predictable postoperative pain. The present study was designed to evaluate the effect of intraoperative administration of propacetamol during remifentanil-based anesthesia on postoperative pain in patients undergoing reduction mammoplasty.

The hypothesis was the reduction of postoperative morphine consumtion and pain after intraoperative administration of propacetamol

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised placebo controlled parallel group trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Morphine consumption and postoperative pain after intraoperative administration of placebo or propacetamol

Interventions
Intraoperative administration of propacetamol or placebo

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Propacetamol

Primary outcome measure
Cumulative dose of morphine administered in the recovery room.

Secondary outcome measures
The secondary end-points were the pain score after tracheal extubation and one hour after, the delay for obtaining a Simplified Numerical Pain Scale (SNPS) less than 4, and the incidence of morphine side effects in the recovery room.

Overall study start date
01/03/2000

Completion date
31/10/2001

Eligibility

Key inclusion criteria
1. Informed consent adult women above 18 years
2. American Society of Anesthesiologists (ASA) I and II

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
36

Key exclusion criteria
1. Preoperative use of analgesic drugs
2. Body mass index ≥ 35
3. American Society of Anesthesiology physical status ≥ 3
4. Sensitivity to paracetamol

Date of first enrolment
01/03/2000

Date of final enrolment
31/10/2001

Locations

Countries of recruitment
France

Study participating centre
Hopital Henri Mondor
Creteil
France
94010

Sponsor information

Organisation
Fight Against Pain Committee (Comité de Lutte contre la Douleur [CLUD]) (France)

Sponsor details
Hopital Henri Mondor
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Sponsor type
Other

ROR
https://ror.org/033yb0967

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Henri Mondor Hospital (Hopital Henri Mondor) (France) - Department of Anaesthesiology

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	14/09/2004		Yes	No