

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	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 27/08/2004	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 13/08/2009	Condition category Surgery	<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Michele Binhas

Contact details
Hopital Henri Mondor
Creteil
France
94010
michele.binhas@hmn.ap-hop-paris.fr

Additional identifiers

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 remifentanyl 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 remifentanyl-based anesthesia on postoperative pain in patients undergoing reduction mammoplasty.

The hypothesis was the reduction of postoperative morphine consumption 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

Study type(s)

Treatment

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(s)

Cumulative dose of morphine administered in the recovery room.

Key secondary outcome(s)

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.

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

Female

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)

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

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