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Non-steroidal anti-inflammatory drug (NSAID) use in breast surgery: prospective randomised trial

Submission date 15/05/2005	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 12/09/2005	**Overall study status** Completed	
Last Edited 30/07/2008	**Condition category** Cancer	

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
Modification of drainage volume after NSAID administration

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Breast cancer

Interventions
Before entering operating room for breast cancer patients are randomised into two groups:
1. NSAID
2. Placebo

Intervention Type
Drug

Phase
Not Specified

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

Primary outcome measure
Total volume drained after modified radical mastectomy

Secondary outcome measures

Breast surgery complications

Overall study start date
01/04/2005

Completion date
30/11/2005

Eligibility

Key inclusion criteria
Eligible patienst are women with a breast cancer undergoing modified radical mastectomy

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
100

Key exclusion criteria
1. Known allergy or contraindication to NSAID
2. Planned immediate or late breast reconstruction

Date of first enrolment
01/04/2005

Date of final enrolment
30/11/2005

Locations

Countries of recruitment
Tunisia

Study participating centre
71, rue Ch Kallala
Sousse
Tunisia
4011

Sponsor information

Organisation
Farhat Hached University Teaching Hospital (Tunisia)

Sponsor details
Boulevard M. Karoui
Sousse
Tunisia
4001

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/0059hys23

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Farhat Hached University Teaching Hospital (Tunisia)

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?
Abstract results	Abstract:	17/11/2006		No	No