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

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

# Plain English summary of protocol

Not provided at time of registration

# Contact information

# Type(s)

Scientific

#### Contact name

Dr Samir Hidar

#### Contact details

71, rue Ch Kallala Sousse Tunisia 4011

# 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