

Effect of an information leaflet about surgical wound infection (SWI) on recollection of information and satisfaction of patients operated on for scheduled surgery

Submission date 12/04/2008	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 30/07/2008	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 30/07/2008	Condition category Infections and Infestations	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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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

Supplying patients who are scheduled to be operated on with a leaflet about surgical wound infection (SWI) could influence recollection of information, satisfaction regarding information and patient's opinion regarding SWI.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval was not required as this study involved only usual processes of care; neither invasive procedures nor medical interventions were involved.

Study design

Single-centre, randomised, single-blind trial.

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Not Specified

Participant information sheet

Health condition(s) or problem(s) studied

Surgical wound infection

Interventions

According to the French regulation, no formal approval was required from the patient. To avoid memorisation bias, patients were told that the subject of the study was quality of care, and not information. They were asked if they agreed to be interviewed by phone 5 weeks after surgery about quality of their care.

Intervention group: Patients received oral information about surgical wound infection from the surgeon plus an information leaflet.

Control group: Patients received only oral information about surgical wound infection from the surgeon.

Both oral information and the leaflet were given to the patients before surgery, during an outpatient visit with the surgeon.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Patients' satisfaction concerning information about surgical wound infection, assessed by a telephone interview 5 +/- 1 week after surgery.

Secondary outcome measures

The following were assessed by a telephone interview 5 +/- 1 week after surgery:

1. Recollection of information
2. Attitude towards surgery and surgical wound infection

Overall study start date

30/09/2005

Completion date

01/04/2007

Eligibility**Key inclusion criteria**

1. Aged over 18 years, both males and females
2. Patients scheduled for surgery in the Digestive Surgery Department of the Rouen University Hospital

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

200

Key exclusion criteria

1. Patients younger than 18 years
2. Patients requiring an emergency surgery
3. Patients with literacy difficulties or with cognitive impairment

4. Patients who do not speak French
5. Patients refusing to be interviewed 5 weeks after surgery

Date of first enrolment

30/09/2005

Date of final enrolment

01/04/2007

Locations

Countries of recruitment

France

Study participating centre

Department of Epidemiology and Public Health

Rouen

France

76031

Sponsor information

Organisation

Rouen University Hospital (France)

Sponsor details

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Sponsor type

University/education

Website

<http://www.chu-rouen.fr>

ROR

<https://ror.org/04cdk4t75>

Funder(s)

Funder type

University/education

Funder Name

Rouen University Hospital (France)

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