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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

Registration date
30/07/2008

Overall study status
Completed

Last Edited
30/07/2008

Condition category
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

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
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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secretariat.DRC@chu-rouen.fr

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