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

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr Véronique Merle

Contact details

Department of Epidemiology and Public Health Rouen University Hospital Rouen France 76031 veronique.merle@chu-rouen.fr

Additional identifiers

Protocol serial number 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

Study type(s)

Not Specified

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(s)

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

Key secondary outcome(s))

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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)

ROR

https://ror.org/04cdk4t75

Funder(s)

Funder type

University/education

Funder Name

Rouen University Hospital (France)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration