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Multicentre study of the reduction of steps (measured by an electronic pedometer) after 4 different types of repair for inguinal hernia

Submission date 29/05/2008	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 20/06/2008	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 20/06/2008	**Condition category** Digestive System	[_] 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
B.U.N. B14320072331

Study information

Scientific Title
Multicentre cohort study evaluating ambulatory activity reduction after LIchtenstein, laparoscopic Totally ExtraPeritoneal, KUgel patch or Polysoft repair of primary inguinal hernia (LITEKUP trial)

Acronym
LITEKUP trial

Study objectives
To compare the short-term functional outcome after four different techniques of inguinal hernia repair in an ambulatory setting, namely, the Lichtenstein repair, the laparoscopic totally extraperitoneal repair, the open retroperitoneal Kugel patch repair and the Polysoft® patch repair.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Leading Ethical Committee of the University Hospital Brussels (Universitair Ziekenhuis Brussel). Date of approval: 11/10/2007

Study design
Prospective, multicentre, cohort, observational study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Inguinal hernia

Interventions
This is an observational cohort study comparing the reduction in ambulatory activity (RAA) after four common techniques of inguinal hernia repair of patients with primary inguinal hernia. The four techniques are:
1. Lichtenstein repair

2. Laparoscopic totally extraperitoneal repair
3. Open retroperitoneal Kugel patch repair
4. Polysoft® patch repair

Count of steps will be carried out 1 week before and 2 weeks after scheduled inguinal hernia repair, measured with an electronic pedometer.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Count of steps 1 week before and 2 weeks after scheduled inguinal hernia repair, measured with an electronic pedometer.

Secondary outcome measures
1. Recurrence rate after 12-24 months. This will be assessed by clinical examination during clinical follow-up after 2 weeks, 6, 12 and 24 months. Independent examination will be performed at 12 and 24 months to assess recurrence and chronic pain.
2. Acute pain at the affected groin side measured daily the week before, the day of and the first 2 weeks after surgery, using a visual analogue scale (VAS) indicating no pain at 0 mm and worst pain ever experienced at 100 mm.
3. Chronic groin pain syndrome at the operated side after 12-24 months. Classified as follows:
No pain: no discomfort experienced
Mild pain: defined to the patient as discomfort that did not limit activity, with a return to pre-hernia lifestyle
Moderate pain: defined as pain preventing return to normal preoperative activities (i.e. inability to continue with prehernia activities such as golf, tennis and other sports, and inability to lift objects, without pain, that patient had been lifting before the hernia occurrence)
Severe pain: pain that incapacitated the patient at frequent intervals or interfered with activities of daily living (i.e. pain constantly present or intermittently present but so severe as to impair normal activities, such as walking)

Overall study start date
01/06/2008

Completion date
31/05/2012

Eligibility

Key inclusion criteria
Consecutive patients (both males and females, >18 years of age) with a diagnosis of primary unilateral inguinal hernia presenting in the participating centres for the surgical repair of their hernia in an ambulatory setting.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
976

Key exclusion criteria
1. Incarcerated inguinal hernia
2. Life expectancy less than two years
3. Pregnancy
4. American Society of Anaesthesiology (ASA) class IV or V
5. Extensive lower abdominal surgery or severe local inflammation
6. Inability to sign the informed consent.
7. Indication for other type of surgery for various reasons
8. Patients unable to walk (paralysed or bedridden patients)
9. Bilateral hernia repair
10. Large scrotal hernias
11. Concomitant abdominal surgery
12. Body mass index (BMI) >= 35 kg/m2
13. Liver cirrhosis (Child C)
14. Known abuse of alcohol or drugs
15. Ongoing long term analgesic or steroid treatment
16. Patients under clopidogrel or warfarin must be switched to subcutaneous (sc) low-molecular-weight (lmw) heparin
17. Severely compromised physical or psychological health, that in the investigators opinion will affect patients compliance
18. Concurrently participating in another clinical trial

Date of first enrolment
01/06/2008

Date of final enrolment
31/05/2012

Locations

Countries of recruitment
Belgium

Study participating centre

Laarbeeklaan 101
Brussels
Belgium
1090

Sponsor information

Organisation
Royal Belgian Society of Surgery, Section of Abdominal Wall Surgery (BSAWS) (Belgium)

Sponsor details
Koninklijk Belgisch Genootschap voor Heelkunde
W. Churchill-laan 11/30
Brussels
Belgium
1180
amb@skynet.be

Sponsor type
Hospital/treatment centre

Website
http://www.belsurg.org

ROR
https://ror.org/04yy1mz94

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Royal Belgian Society of Surgery, Section of Abdominal Wall Surgery (BSAWS) (Belgium)

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