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Conventional open versus laparoscopic surgery for peritoneal dialysis (PD) peritonitis

Submission date 19/10/2009	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 30/11/2009	**Overall study status** Completed	
Last Edited 02/10/2017	**Condition category** Digestive System	

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
UHL 10636

Study information

Scientific Title
A randomised controlled trial of conventional open versus laparoscopic surgery for peritoneal dialysis (PD) peritonitis

Study objectives
Peritoneal dialysis (PD) may be complicated by the development of peritonitis and this problem has an incidence of approximately 1.5 episodes per patient in year one. All patients with PD peritonitis are all admitted under the care of the nephrology team and the vast majority are treated by conservative measures. This involves the administration of intraperitoneal (IP) antibiotics in a large single dose of vancomycin and oral ciprofloxacin. Some patients are also given intravenous (IV) antibiotics, chosen according to the results of microbiological analysis of the infected PD fluid. In certain circumstances these patient require surgery to treat this infection.

The trial has been designed to test the safety and efficacy of the laparoscopic operation in comparison with the traditional open procedure. The primary outcome measure will be post-operative pain levels and analgesic requirements.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Leicestershire, Northamptonshire and Rutland Research Ethics Committee 2, 30/01/2009, ref: 08/H0402/132

Study design
Randomised controlled single-centre trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Peritoneal dialysis (PD) peritonitis

Interventions
Laparoscopic versus conventional open PD catheter removal and peritoneal lavage for PD peritonitis.

Intervention Type
Procedure/Surgery

Primary outcome measure
Post-operative pain levels and analgesic requirements. The following outcome data are collected:
1. Duration of the surgical operation (time from first incision to last skin suture)
2. Post-operative pain levels and analgesic requirements:
2.1. Pain assessed daily using a linear analogue scale (100 mm line with 'no pain at all' written at the left hand (zero) end and 'worst pain imaginable' written at the right hand (100) end
2.2. Post-operative analgesic use recorded by the nursing staff and pain team using the standard PCAS (Patient Controlled Analgesia System) form. This includes the total dose of morphine used in mg and the duration of PCAS use in hours

Secondary outcome measures
Return to normal activities and post-operative respiratory function.

1. Resumption of normal activities:
1.1. In-patient assessment includes grip strength, measured pre operatively then daily whilst an in-patient and in the clinic one and three months postoperatively. The timed Up and Go measured pre operatively, then at three and five days post operatively, at discharge, then at the one and three monthly clinic visits (patients are timed as they rise from a standard chair, walk 3 metres, turn, walk back and sit). The duration of post-operative in-patient stay is also recorded.
1.2. At the time of discharge, patients are assessed on their Activities of Daily Living (ADL) 6 by scoring the following activities on a 3 point scale. (1: no help needed, 2: needing help, 3: unable to do). An assessment is also made pre operatively:
1.2.1. Grooming
1.2.2. Feeding
1.2.3. Toileting
1.2.4. Bathing
1.2.5. Dressing
1.2.6. Transferring from bed to chair
1.2.7. Walking across a room
These are then assessed again at the one and three monthly clinic appointments.

2. Respiratory function:
2.1. Assessed preoperatively and on the first, third and fifth postoperative days by spirometry (Forced expiratory volume in one second [FEV1] and forced vital capacity [FVC]).

3. The metabolic response to surgery:
3.1. Investigated by daily measurements of C-reactive protein and plasma cytokine levels (tumour necrosis factor-α [TNF-α]; interleukin-1 [IL-1] and IL-6).

4. Complication rates:
4.1. This includes mortality, wound complications (infection, hernia), chest complications (infection, pneumonia, atelectesis), thrombo-embolic disease (deep vein thrombosis, pulmonary embolism) and any other adverse event. Re-operation rates for persisting infection are also recorded.

5. Post operative recovery:
5.1. The Multidimensional Fatigue Inventory (MFI-20) is given to the patient at the one and three

month clinic visit 7. The questionnaire assesses general fatigue, physical, reduced activity, reduced motivation and mental fatigue.
5.2. More complex care abilities are assessed pre operatively then at the one and three monthly clinic visits using the Instrumental Activities of Daily Living scale (IADL) 6, again on a 3-point scale:
5.2.1. Using the telephone
5.2.2. Accessing transportation away from home
5.2.3. Shopping
5.2.4. Preparing meals
5.2.5. Housework
5.2.6. Laundry
5.2.7. Managing medication
5.2.8. Managing finances

Overall study start date
10/10/2009

Completion date
10/10/2012

Eligibility

Key inclusion criteria
1. Any patient (both males and females) 18 years or over presenting with PD peritonitis requiring surgery referred by a nephrologist to the surgical team as defined below:
1.1. Failure of the medical treatment described above i.e. refractory peritonitis. In these cases the use of appropriate IP/IVantibiotics fails to improve the patient's clinical condition (pain and abdominal tenderness) and the turbid effluent PD fluid doesn't become clear, suggesting that infection is ongoing. There may also be signs of systemic sepsis with persistent tachycardia, pyrexia, a raised white count and a raised C reactive protein
1.2. Clinical signs of generalised peritonitis: generalised severe abdominal tenderness with rigidity, rebound tenderness and loss of bowel sounds
1.3. Peritonitis caused by pseudomonas species
1.4. Fungal peritonitis
2. The above patients that are not already included in a clinical trial
3. The above patients that consent to participate in the trial

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants

Key exclusion criteria
1. Patients from which formal consent cannot be taken
2. Patients with poor respiratory function that may be put at risk by laparoscopic surgery as assessed by an anaesthetist
3. Patients that have had multiple laparotomy procedures and history of adhesions as a result of the surgery

Date of first enrolment
10/10/2009

Date of final enrolment
10/10/2012

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University Hospitals of Leicester
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Sponsor information

Organisation
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Sponsor type
Hospital/treatment centre

Website
http://www.uhl-tr.nhs.uk/

ROR
https://ror.org/02fha3693

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
University Hospitals of Leicester NHS Trust (UK)

Funder Name
University of Leicester (UK)

Alternative Name(s)
UoL

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

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