

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

Submission date 19/10/2009	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 30/11/2009	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 02/10/2017	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

Contact name
Prof Michael Nicholson

Contact details
Transplant Group
University Hospitals of Leicester
Leicester General Hospital
Leicester
United Kingdom
LE5 4PW

Additional identifiers

Protocol serial number
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

Primary study design

Interventional

Study design

Randomised controlled single-centre trial

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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, atelectasis), 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

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/IV antibiotics 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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

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

United Kingdom

England

Study participating centre
University Hospitals of Leicester
Leicester
United Kingdom
LE5 4PW

Sponsor information

Organisation
University Hospitals of Leicester NHS Trust (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)
UniofLeicester, UoL

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary