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Steroid tape to treat overgranulating peritoneal dialysis catheter exit sites

Submission date	Recruitment status	[_] Prospectively registered
08/01/2015	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
08/01/2015	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
20/05/2022	Urological and Genital Diseases	

Plain English summary of protocol

Background and study aims
Kidney failure is a devastating illness where the kidneys no longer function properly, requiring treatment with dialysis or transplantation to preserve life. Patients unable to have transplants are managed by peritoneal dialysis or haemodialysis. Peritoneal dialysis involves the placement of a soft, flexible plastic tube (catheter) into the abdomen, allowing dialysis fluid to be drained in and out of the peritoneal cavity, in order to remove waste products from the blood. The catheter exits from a hole in the abdomen and occasionally patients can have complications at this exit site. One possible complication is overgranulation. Overgranulation occurs as the wound attempts to heal and the skin around the exit site becomes red, 'wet', 'bumpy' and stands 'proud' of the surrounding skin. An overgranulating exit site can lead to discomfort, pain, bleeding and harbour infection. More serious complications include dialysis failure, sepsis and death. There are several ways to treat overgranulation but there is limited research evidence to demonstrate which treatment is best. The aim of this study is to determine the safety and effectiveness of steroid-impregnated tape compared to standard treatment with silver nitrate.

Who can participate?
Patients aged over 18 on peritoneal dialysis who have an overgranulating exit site

What does the study involve?
Participants are randomly allocated to receive either the current standard treatment, which involves the application of silver nitrate by qualified nursing staff to chemically burn the tissue away, or an alternative treatment which involves the patient themselves applying a steroid-impregnated tape. The severity of over-granulation is assessed after 14 days.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
University Hospital Birmingham NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
December 2013 to August 2016

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
Nicola Anderson

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number
2013-003867-76

IRAS number

ClinicalTrials.gov number
NCT01996930

Secondary identifying numbers
15417

Study information

Scientific Title
A prospective, randomised controlled trial to determine the safety and efficacy of steroid impregnated tape compared to standard therapy with silver nitrate in the treatment of overgranulating peritoneal dialysis catheter exit sites

Study objectives
There are several ways to treat overgranulation but there is limited research evidence to demonstrate which treatment is best. The study aims to compare current standard treatment which involves the application of silver nitrate by qualified nursing staff to chemically burn the tissue away, with an alternative treatment which involves the application of a steroid impregnated tape by the patient themselves.

Ethics approval required
Old ethics approval format

Ethics approval(s)
13/WM/0400

Study design
Randomised, interventional

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 below to request a patient information sheet

Health condition(s) or problem(s) studied
Topic: Renal disorders; Subtopic: Renal disorders; Disease: All Renal disorders

Interventions
1. Haelan tape
2. Steroid Impregnated tape

Intervention Type
Procedure/Surgery

Primary outcome measure
Complete response rate in over-granulation severity; Timepoint(s): 14 days

Secondary outcome measures
N/A

Overall study start date
01/12/2013

Completion date
30/08/2016

Eligibility

Key inclusion criteria

1. Subject has been established on Peritoneal Dialysis for > 3 months
2. Subject has an over-granulating exit site judged to require treatment according to standard
3. If patient has exit site infection, they must currently be treated with antibiotics and the site must be clinically improving.
4. Subject is > 18 years of age
5. Subject is able to give informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 80; UK Sample Size: 80

Key exclusion criteria
1. Subject has had peritonitis treated in the previous month
2. Subject has been treated with silver nitrate or topical steroids in the previous 2 weeks
3. Subject is receiving oral steroids
4. Patient is unable to give informed consent
5. Patient is participating in a clinical trial of an intervention relating to PD catheters
6. Subject is pregnant or unwilling to use an effective method of contraception during the course of the study

Date of first enrolment
01/12/2013

Date of final enrolment
30/08/2016

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Department of Primary Care & General Practice
Birmingham
United Kingdom
B15 2TT

Sponsor information

Organisation
University Hospital Birmingham NHS Foundation Trust

Sponsor details
Renal Department
Birmingham
England
United Kingdom
B15 2TH

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/014ja3n03

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

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
Not provided at time of registration

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results		28/08/2021	20/05/2022	No	No
HRA research summary			28/06/2023	No	No