

Steroid tape to treat overgranulating peritoneal dialysis catheter exit sites

Submission date 08/01/2015	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 08/01/2015	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 20/05/2022	Condition category Urological and Genital Diseases	<input type="checkbox"/> Individual participant data

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

ClinicalTrials.gov (NCT)
NCT01996930

Clinical Trials Information System (CTIS)
2013-003867-76

Protocol serial number
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

Primary study design

Interventional

Study design

Randomised, interventional

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

N/A

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

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

United Kingdom

England

Study participating centre

Department of Primary Care & General Practice

Birmingham

United Kingdom

B15 2TT

Sponsor information

Organisation

University Hospital Birmingham NHS Foundation Trust

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

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