# Steroid tape to treat overgranulating peritoneal dialysis catheter exit sites

<b>Recruitment status</b> No longer recruiting	Prospectively registered		
	☐ Protocol		
Overall study status	Statistical analysis plan		
Completed	[X] Results		
Condition category	[] Individual participant data		
	No longer recruiting  Overall study status  Completed		

#### 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

Mrs Nicola Anderson

#### Contact details

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### Additional identifiers

Clinical Trials Information System (CTIS)

2013-003867-76

ClinicalTrials.gov (NCT)

NCT01996930

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

#### Study design

Randomised, interventional

#### Primary study design

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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes