# A randomised open label placebo study to evaluate the use of Solcogyn applied topically to the cervix in women referred for the assessment of cervical low grade introepithelial lesions

| Submission date   | Recruitment status              | <ul><li>Prospectively registered</li></ul> |
|-------------------|---------------------------------|--|
| 12/09/2003        | No longer recruiting            | ☐ Protocol                                 |
| Registration date | Overall study status            | Statistical analysis plan                  |
| 12/09/2003        | Completed                       | Results                                    |
| Last Edited       | Condition category              | Individual participant data                |
| 30/04/2015        | Urological and Genital Diseases | Record updated in last year                |

# Plain English summary of protocol

Not provided at time of registration

# Contact information

# Type(s)

Scientific

#### Contact name

Miss Karen Easton

#### Contact details

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# Additional identifiers

Protocol serial number N0106110085

# Study information

## Scientific Title

A randomised open label placebo study to evaluate the use of Solcogyn applied topically to the cervix in women referred for the assessment of cervical low grade intro-epithelial lesions

# **Study objectives**

To determine if treatment of a cervical ectopy associated with minor cytological abnormalities but no colposcopic evidence of high grade dysplasia results in a better clearance rate in terms of normal cytology at 6 month follow up than in the placebo controlled group.

# Ethics approval required

Old ethics approval format

# Ethics approval(s)

Not provided at time of registration

# Study design

Randomised open-label placebo study

## Primary study design

Interventional

# Study type(s)

**Treatment** 

# Health condition(s) or problem(s) studied

Dysplasia

#### **Interventions**

- 1. Placebo (saline)
- 2. Solcogyn

## Intervention Type

Drug

#### Phase

**Not Specified** 

# Drug/device/biological/vaccine name(s)

Solcogyn

## Primary outcome(s)

Increased number of patients returning to normal cytology after six months of treatment.

## Key secondary outcome(s))

Not provided at time of registration

# Completion date

19/09/2003

# **Eligibility**

# Key inclusion criteria

106 women aged 20-50 attending the colposcopy clinic with cytological abnormalities showing borderline or mild changes and who also have a cervical ectopy.

# Participant type(s)

**Patient** 

## Healthy volunteers allowed

No

# Age group

Adult

## Sex

Female

## Key exclusion criteria

Not provided at time of registration

## Date of first enrolment

19/03/2002

# Date of final enrolment

19/09/2003

# Locations

## Countries of recruitment

**United Kingdom** 

**England** 

# Study participating centre Gloucestershire Royal Hospital

Gloucester United Kingdom GL1 3NN

# **Sponsor information**

## Organisation

Department of Health (UK)

# Funder(s)

# Funder type

Government

# Funder Name

Gloucestershire Research and Development Consortium (UK)

# **Results and Publications**

Individual participant data (IPD) sharing plan

# IPD sharing plan summary

Not provided at time of registration