# Randomised controlled trial of condoms plus additional lubrication

| Submission date   | Recruitment status  No longer recruiting | Prospectively registered       |  |  |
|-------------------|--|--------------------------------|--|--|
| 23/01/2004        |  | ☐ Protocol                     |  |  |
| Registration date | Overall study status                     | Statistical analysis plan      |  |  |
| 23/01/2004        | Completed                                | [X] Results                    |  |  |
| Last Edited       | Condition category                       | [] Individual participant data |  |  |
| 08/09/2014        | Pregnancy and Childbirth                 |                                |  |  |

#### Plain English summary of protocol

Not provided at time of registration

#### Contact information

## Type(s)

Scientific

#### Contact name

Dr Mark Gabbay

#### Contact details

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# Additional identifiers

Protocol serial number RHC18067

# Study information

Scientific Title

#### **Study objectives**

Does the application of additional spermicidal lubrication to condoms reduce the risk of condom failure amongst couples?

#### Ethics approval required

Old ethics approval format

#### Ethics approval(s)

Not provided at time of registration

#### Study design

Randomised controlled crossover trial

#### Primary study design

Interventional

#### Study type(s)

Prevention

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

Contraception

#### **Interventions**

- 1. Use of condoms only
- 2. Use of condoms with additional spermicide

#### Intervention Type

Other

#### Phase

Not Applicable

#### Primary outcome(s)

Condom failure

#### Key secondary outcome(s))

Not provided at time of registration

#### Completion date

01/07/2001

# **Eligibility**

#### Key inclusion criteria

Couples over the age of 18 years and intend to use condoms regularly and who do not use additional lubricant with them.

#### Participant type(s)

**Patient** 

#### Healthy volunteers allowed

No

#### Age group

Adult

#### Lower age limit

18 years

#### Sex

All

#### Key exclusion criteria

- 1. Subjects who are not willing to be randomised or to use additional lubricant with their condoms
- 2. Subjects unlikely to allow follow-up or co-operate with outcome data collection
- 3. Subjects without a regular partner
- 4. Couples with a known sensitivity to spermicides or latex
- 5. Couples who are not intending to use condoms at least predominantly for vaginal intercourse

#### Date of first enrolment

01/10/1997

#### Date of final enrolment

01/07/2001

### Locations

#### Countries of recruitment

United Kingdom

England

# Study participating centre University of Liverpool

Liverpool United Kingdom L69 3GB

# Sponsor information

#### Organisation

NHS R&D Regional Programme Register - Department of Health (UK)

# Funder(s)

#### Funder type

Government

#### Funder Name

NHS Executive North West (UK)

# **Results and Publications**

Individual participant data (IPD) sharing plan

#### IPD sharing plan summary

Not provided at time of registration

#### **Study outputs**

| Output type     | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|-----------------|---------|--------------|------------|----------------|-----------------|
| Results article | results | 01/10/2008   |            | Yes            | No              |