

Randomised controlled trial of condoms plus additional lubrication

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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