ISRCTN59655786 https://doi.org/10.1186/ISRCTN59655786

Randomised controlled trial of condoms plus additional lubrication

Submission date	Recruitment status
23/01/2004	No longer recruiting
Registration date	**Overall study status**
23/01/2004	Completed
Last Edited	**Condition category**
08/09/2014	Pregnancy and Childbirth

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Prevention

Participant information sheet

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 measure
Condom failure

Secondary outcome measures

Not provided at time of registration

Overall study start date
01/10/1997

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
145 couples

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
England

United Kingdom

Study participating centre
University of Liverpool
Liverpool
United Kingdom
L69 3GB

Sponsor information

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

Sponsor details
The Department of Health
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL
+44 (0)20 7307 2622
dhmail@doh.gsi.org.uk

Sponsor type
Government

Website
http://www.doh.gov.uk

Funder(s)

Funder type
Government

Funder Name
NHS Executive North West (UK)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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