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Effectiveness of BenZalKonium chloride gel as vaginal contraceptive: a multicentric randomised controlled trial

Submission date	Recruitment status	[_] Prospectively registered
19/05/2008	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
29/05/2008	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
28/01/2019	Pregnancy and Childbirth	

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
NCT00692952

Secondary identifying numbers
Chinese State Food And Drug Administration, Clinical Trial Permission No. 2003L02778

Study information

Scientific Title
Effectiveness of BenZalKonium chloride gel as vaginal contraceptive: a randomised controlled trial among Chinese women

Acronym
BZK contraceptive gel

Study objectives
A multicentric clinical trial in three Chinese Maternal and Child Hospitals was conducted to evaluate the efficacy, safety and acceptability of a newly-developed vaginal contraceptive gel, the optimised benzalkonium chloride (BZK) gel containing 18 mg BZK, with comparison to a currently marketed (in China) contraceptive gel Lelemi® containing 50 mg Nonoxynol-9 (N-9).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the Ethical Committee of International Peace Maternity and Child Care Centre, Shanghai (P.R. China) on the 5th March 2004.

Study design
Phase II multicentric randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Contraceptive effectiveness

Interventions
Participants received either benzalkonium chloride gel or nonoxynol-9 gel as their primary method of contraception. All treatment arms were followed for six months.

The test drug, Benzakonium Chloride Contraceptive Gel (Brand name: Konrapo spermicide gel), was provided by Shanghai Institute of Planned Parenthood Research and Changjiang Bio-pharmaceutical Co. Ltd. 4.2 ml 0.429% BZK gel is filled in a disposable applicator for single use (18 mg BZK per piece), Lot No. 20040108. The gel is ready to use and should be inserted into

vagina before every coital act. The drug action lasts for 24 hours, however, it is recommended to finish the coital act within 4 hours.

The control drug, Nonoxyno-9 Contraceptive Gel (Lelemi® Contraceptive Gel), was provided by Pharmaceutical Co. Ltd, Chinese Pharmaceutical University. Each piece of gel contains 50 mg N-9. The gel should be inserted into vagina within half an hour before each sexual intercourse. After the insertion, women are not allowed to walk and the sexual intercourse should be finished within half an hour. Otherwise, another piece should be inserted.

Intervention Type
Drug

Phase
Phase II

Drug/device/biological/vaccine name(s)
Benzalkonium chloride (BZK), nonoxynol-9 (Lelemi®)

Primary outcome measure
Contraceptive effectiveness. Outcomes were assessed at 2, 4 and 6-month follow-up visits.

Secondary outcome measures
1. Safety, evaluated based on gynaecological examination, cytobacteriological examinations, blood test, urine test, reporting adverse events, and termination due to medical reasons. An adverse event was a change in health status from that at baseline, regardless of its possible relationship with the product, consistent with good clinical practice guidelines.
2. Product acceptability, assessed through a standard questionnaire

Outcomes were assessed at 2, 4 and 6-month follow-up visits.

Overall study start date
01/03/2004

Completion date
01/11/2005

Eligibility

Key inclusion criteria
Eligibility requirements included:
1. Sexually active female
2. Aged 20 - 45 years old
3. Presumably fertile based on at least one delivery record
4. At risk for pregnancy and desiring contraception
5. Having regular menstrual cycle (21 - 35 days) and at least three normal menstrual cycles since the last pregnancy, abortion or hormone contraceptive use
6. Be willing to engage in at least four acts of sexual intercourse per month
7. Use the test products as their primary method of contraception
8. Keep a diary of coital activity, product use, and adverse events
9. At low risk for human immunodeficiency virus (HIV) or other sexually transmitted infection,

which was defined as having a single sexual partner (for at least six months prior to study initiation)
10. The subject's sexual partner should not be presumably infertile, have a known allergy to BZK or N-9, or have been treated for sexually transmitted diseases (STDs) within six months prior to study entry

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
200

Key exclusion criteria
Exclusion criteria included:
1. Diagnosis of any vaginal infection or any symptom of STDs at baseline
2. Known allergy or hypersensitivity to N-9 or BZK
3. Menopause for more than one month
4. Breastfeeding
5. Vaginal bleeding with unknown reasons
6. Recurrent vaginitis or urinary infection
7. Genitourinary system anomaly
8. Hysteroptosis II or severe cystocele
9. Moderate to severe erosion of cervix
10. Malignant reproductive system tumours

Date of first enrolment
01/03/2004

Date of final enrolment
01/11/2005

Locations

Countries of recruitment
China

Study participating centre
Shanghai Institute of Planned Parenthood Resarch
Shanghai
China
200032

Sponsor information

Organisation
Shanghai Institute of Planned Parenthood Research (China)

Sponsor details
World Health Organization (WHO) Collaborating Centre for Research in Human Reproduction
2140 Xie Tu Road
Shanghai
China
200032

Sponsor type
Research organisation

ROR
https://ror.org/03awxj939

Funder(s)

Funder type
Research organisation

Funder Name
Shanghai Institute of Planned Parenthood Research (China) - World Health Organization (WHO) Collaborating Centre for Research in Human Reproduction

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	01/06/2013	28/01/2019	Yes	No