

A randomised controlled trial of lactobacillus in general practice to prevent post-antibiotic vulvovaginitis

Submission date 08/10/2002	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 08/10/2002	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 07/03/2008	Condition category Infections and Infestations	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

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

2001/524 (number assigned by the Therapeutic Goods Administration in Australia)

Study information

Scientific Title

Acronym

PAV (post-antibiotic vulvovaginitis)

Study objectives

This study aims to test in a randomised controlled trial whether oral and/or vaginal lactobacillus preparations can prevent post-antibiotic vulvovaginitis.

Ethics approval required

Old ethics approval format

Ethics approval(s)

The trial has received ethics approval from both the Royal Australian College of General Practitioners and the Royal Women's Hospital, Melbourne, Australia.

Study design

Randomised controlled blinded 2 x 2 factorial design, with four intervention groups

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Prevention

Participant information sheet

Health condition(s) or problem(s) studied

Post-antibiotic vulvovaginitis

Interventions

Factorial design to test oral and vaginal lactobacillus species.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Lactobacillus

Primary outcome measure

The primary outcome is symptomatic vulvovaginal candidiasis, defined as:

1. Participants' report of symptoms (that is answer 'yes' to a question about symptoms of 'thrush' in survey 2: vaginal itch, irritation with or without a discharge)
2. Swab B culture positive for Candida species

Secondary outcome measures

No secondary outcome measures

Overall study start date

01/07/2004

Completion date

31/12/2005

Eligibility

Key inclusion criteria

1. Women aged between 18 and 50 years of age
2. Who are experiencing a non-genital infection
3. Requiring a short-course of oral antibiotics or have commenced this within the 48 hours preceding enrolment
4. English-speaking: able to speak, read and write in English sufficiently to provide informed consent and complete surveys

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Female

Target number of participants

496

Key exclusion criteria

1. Pregnancy
2. Experiencing any vaginal symptoms at recruitment
3. Unwilling or unable to provide two self-collected low vaginal swabs (at recruitment and on completion of trial)
4. Using or have used vaginal antifungal treatments in the past two weeks
5. Have taken antibiotics in the past month
6. Unwilling to stop taking other lactobacillus products during the trial

7. Immunocompromised, as there are rare reports in the literature of lactobacilli causing endocarditis and bacteraemia

Date of first enrolment

01/07/2004

Date of final enrolment

31/12/2005

Locations

Countries of recruitment

Australia

Study participating centre

Department of General Practice

Carlton

Australia

3053

Sponsor information

Organisation

University of Melbourne (Australia)

Sponsor details

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Victoria

Australia

3010

Sponsor type

University/education

Website

<http://www.unimelb.edu.au>

ROR

<https://ror.org/01ej9dk98>

Funder(s)

Funder type

Charity

Funder Name

Shepherd Foundation (Australia)

Funder Name

Royal Australian College of General Practitioners (Australia) (ref: 00/58)

Alternative Name(s)

RACGP

Funding Body Type

Private sector organisation

Funding Body Subtype

Associations and societies (private and public)

Location

Australia

Funder Name

Department of Health and Aged Care (Australia) - scholarship for Dr Pirotta

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?
Protocol article	Protocol	28/03/2004		Yes	No