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

Submission date 08/10/2002	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 08/10/2002	**Overall study status** Completed	
Last Edited 07/03/2008	**Condition category** Infections and Infestations	

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. Rrequiring 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
-
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