ISRCTN23587778 https://doi.org/10.1186/ISRCTN23587778

The FARINGOCAT study: rapid antigen detection testing in acute pharyngitis

Submission date	Recruitment status	[_] Prospectively registered
29/01/2008	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
20/03/2008	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
21/09/2011	Respiratory	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Montse Balagué Corbella

Contact details
Portaferrissa 8, ppal
Barcelona
Spain
08002

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
PI061782

Study information

Scientific Title

Rapid antigen detection testing impact on antibiotic use in acute pharyngitis: FARINGOCAT

Acronym
FARINGOCAT

Study objectives
Rapid antigen detection testing would allow a more rational use of antibiotics and would prevent adverse effects of antibiotics on the patient, antibiotic resistance emergence and the growth of inefficient health expense.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Study approved by the Research Ethics Committee of the Jordi Gol i Gurina Primary Care Research Insitute (IDIAP), Barcelona on the 4th July 2006.

Study design
Multicentric randomised clinical assay

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Acute pharyngitis

Interventions
1. Rapid antigen detection (case group)
2. Usual antigen detection (control group)

Treatment will be decided in both groups by the general practitioner. This treatment could be 'nothing', an anti-thermic drug, anti-inflammatory drug and/or an antibiotic.

Intervention Type
Other

Phase

Not Specified

Primary outcome measure
1. Proportion of inadequate antibiotic prescription in each group
2. Use of antibiotic treatment
3. Use of rapid antigen detection testing
4. Rapid antigen detection testing result
5. Culture result

Outcomes will be measured at baseline and three weeks in all patients. If there is a problem, i.e., a secondary effect, then this may take longer.

Secondary outcome measures
1. Clinical symptoms of acute pharyngotonsillitis: fever, tonsillar exudate, cervical adenopathies, absence of cough, measured at baseline and at dates below
2. Age, measured at baseline
3. Antibiotic treatment, measured at baseline and at dates below
4. Specific antibiotic treatment, measured at baseline and at dates below
5. Treatment secondary effects, measured at baseline and at dates below
6. Days without working, measured at baseline and at dates below
7. Medical visits during the first month, measured at week three in all patients, at week four if necessary
8. Patient satisfaction, measured between 3 - 4 weeks after the second visit in one group of patients, between 5 - 7 months in another group of patients

Outcomes will be measured at three weeks in all patients. If there is a problem, i.e., a secondary effect, then this may take longer.

Overall study start date
01/01/2008

Completion date
31/12/2008

Eligibility

Key inclusion criteria
1. Men and women 14 to 60 years old
2. More than one acute pharyngitis symptom, i.e., fever, sore throat, tonsillar exudate, cervical adenopathy and absence of cough, which leads to a visit to the family practice

Participant type(s)
Patient

Age group
Not Specified

Sex
Both

Target number of participants

276 patients per group

Key exclusion criteria
1. Does not consent to participate
2. Patient is younger than 14 or older than 60 years old
3. Pharyngitis more than five times in year
4. Immunodepression: quimiotherapy, radiotherapy, active neoplasia, acquired immune deficiency syndrome (AIDS), corticoids, immunosuppressor treatment
5. Valve heart disease
6. Rheumatoid fever
7. Pharyngitis with previous treatment during 15 days or recurrence of symptoms during 4 weeks after 7 days of complete antibiotic treatment
8. Pharyngitis of diphtheria or gonococcica cause
9. Tonsillectomy

Date of first enrolment
01/01/2008

Date of final enrolment
31/12/2008

Locations

Countries of recruitment
Spain

Study participating centre
Portaferrissa 8, ppal
Barcelona
Spain
08002

Sponsor information

Organisation
Jordi Gol i Gurina Primary Care Research Institute (Institut D'Investigació en Atenció Primària) (IDIAP) (Spain)

Sponsor details
Gran Via de les Corts Catalanes, 587 àtic
Barcelona
Spain
08007

Sponsor type

Research organisation

Website
http://www.idiapjgol.org/

ROR
https://ror.org/0370bpp07

Funder(s)

Funder type
Research organisation

Funder Name
Health Research Fund - Carlos III Health Institute of the Spanish Ministry of Health and Consumption (Fondo de Investigaciones Sanitarias - Instituto de Salud Carlos III-Ministerio de Sanidad y Consumo) (Spain)

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	23/03/2010		Yes	No
Results article	results	01/05/2011		Yes	No