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Developing aspirin tolerance in patients who are allergic/sensitized to aspirin

Submission date
19/01/2022

Recruitment status
No longer recruiting

Registration date
25/01/2022

Overall study status
Completed

Last Edited
04/02/2022

Condition category
Respiratory

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Nonsteroidal exacerbated respiratory disease is a condition where asthma is brought on when taking a type of medication known as a non-steroidal anti-inflammatory, e.g. aspirin.
Aspirin desensitization (AD) is effective in relieving asthma in patients with NERD. So far, only a limited number of studies evaluated the effect of AD prospectively in a controlled manner in NERD. It is also a current approach to recommend endoscopic sinus surgery (ESS) prior to AD. The aim of this study was to prospectively document the clinical effects of AD in patients with NERD for 1 year in the presence of a control group.

Who can participate?
Adult patients with NERD can participate.

What does the study involve?
All participants have ESS before enrolment in the study. Participants of the treatment arm are introduced to aspirin tablets from low to high doses (12.5 -600 mg) for 2-3 days in our inpatient clinic. The patients will be asked to fill in some questionnaires and scoring forms . The asthma control tests, spirometry results, medications and eosinophil counts will be recorded from the patient files. These procedures will repeat at 1st, 6th, and 12th months of the study. The patients will be assessed by an ENT specialist with nasal endoscopy fort he nasal outcomes at the same time points.
The patients in the control arm will have the same schedule above except the aspirin treatment .

What are the benefits and risks of participating?
The possible benefit of participating in the study is the improvement of asthma and nasal outcomes, besides retarding in nasal polyp recurrence.
During the desensitization procedure, allergic reactions can be seen. An allergic reaction during the course is treated by the study investigators. The patients will be followed carefully during the procedure.

Where is the study run from?
Ankara University School of Medicine (Turkey)

When is the study starting and how long is it expected to run for?
August 2008 to August 2009

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Omur Aydin, MD, mdomuraydin@gmail.com

Contact information

Type(s)
Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Aspirin desensitization following endoscopic sinus surgery is effective in patients with NERD: A 1 year prospective and controlled study

Study objectives
Aspirin desensitization is beneficial on clinical outcomes (both asthma and sinonasal outcomes) of patients with nonsteroid exacerbated respiratory disease

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 14/08/2008, Ankara University ethics committee (Ankara University school of medicine, Hacettepe street, Talatpasa square, no: 82, Ankara, Turkey; +90 3125088227; no email provided), ref: 136-3997

Study design
Single center interventional study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
See additional files (in Turkish)

Health condition(s) or problem(s) studied
Aspirin treatment in patients with NERD (non-steroid-exacerbated respiratory disease)

Interventions

The patients are non-randomly divided into 2 arms:
1. Active aspirin treatment arm: The patients in this group are desensitized to aspirin in our clinic for 1 week and tolerate a 600 mg/ daily aspirin.

2. Control arm: The patients in this group are also candidate for aspirin desensitization treatment but this procedure could not be performed due to either the patient had a contraindication for aspirin therapy or the patient did not give informed consent. This group is regularly followed up for routine asthma management.

All cases have endoscopic sinus surgery (ESS) before enrolment to the study. The asthma and rhinosinusitis outcomes are assessed at baseline and at 1 year.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Aspirin

Primary outcome measure
1. Asthma outcomes measured using patient records at 1st, 6th, and 12th months:
1.1 Severe asthma attacks which require at least 3 days of oral corticosteroid treatment
1.2 Hospitalizations due to asthma
1.3 Admission to emergency care and systemic corticosteroid use due to asthma in the last year
1.4. Medication use
1.5 Asthma control measured using the asthma control test
2. Sinonasal outcomes measured using patient records at 1st, 6th, and 12th months:
2.1 Nasal symptom (sneezing, nasal blockage, nasal itching) scores
2.2 Medication use
2.3 Number of sinusitis episodes in the last year
2.4 Number of nasal surgeries due to nasal polyposis in the last year
2.5 Nasal endoscopic findings measured using ENT

Secondary outcome measures
Measured at 1st, 6th, and 12th months:
1. Asthma and rhinitis quality of life questionnaires
2. Pulmonary function tests
3. Eosinophil counts measured using blood test
4. Results of smell tests in the last year measured using olfaction test

Overall study start date
01/08/2008

Completion date
01/08/2009

Eligibility

Key inclusion criteria

1. Aged 18 - 65 years
2. Aspirin hypersensitivity

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
20 participants for patient group and 20 for control group. Total participants are 40

Total final enrolment
44

Key exclusion criteria
1. Pregnancy
2. Patients who are failed to be desensitized with aspirin (ie. anaphylaxis)
3. Patients who have a previous history of gastric bleeding

Date of first enrolment
04/08/2008

Date of final enrolment
29/01/2009

Locations

Countries of recruitment
Türkiye

Study participating centre
Ankara University School of Medicine
Ankara University School of Medicine Chest Disease Department
Dikimevi
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Sponsor information

Organisation
Ankara University

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Sponsor type
Hospital/treatment centre

Website
http://www.medicine.ankara.edu.tr

ROR
https://ror.org/01wntqw50

Funder(s)

Funder type
Industry

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal.

Intention to publish date
15/02/2022

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study will be published as a supplement to the subsequent results publication

IPD sharing plan summary
Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			24/01/2022	No	Yes
Participant information sheet			24/01/2022	No	Yes
Basic results		04/02/2022	04/02/2022	No	No