ISRCTN27745631 https://doi.org/10.1186/ISRCTN27745631

Acetylsalicylic acid as an adjuvant therapy for schizophrenia

Submission date	Recruitment status
16/05/2005	No longer recruiting
Registration date	**Overall study status**
16/05/2005	Completed
Last Edited	**Condition category**
15/06/2010	Mental and Behavioural Disorders

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Huib Burger

Contact details
Department of Epidemiology and Bioinformatics
University Medical Center Groningen
P.O. Box 30001
Groningen
Netherlands
9700 AR
h.burger@epi.umcg.nl

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
NTR29

Study information

Scientific Title

Acronym
Aspirine Trial

Study objectives
Findings from both epidemiological and basic research point to the possibility that non-steroidal anti-inflammatory drugs (NSAIDS) impede the deterioration in schizophrenia.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the Ethical Review Board of the University Medical Center Utrecht.

Study design
Randomised, double blinded, placebo controlled, parallel group 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
Schizophrenia, schizo-affective disorder, schizofreniform disorder

Interventions
Please note that as of 03/06/2008 the anticipated end date of this trial has been updated to 01 /09/2007, when this trial completed recruitment of participants. The previous anticipated end date of this trial was 01/01/2007.

Interventions:
Acetylsalicylic acid 1000 mg versus placebo for 3 months (all receive daily pantoprazol 40 mg).

Intervention Type
Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)
Acetylsalicylic acid, pantoprazol

Primary outcome measure
Three-month change in positive and negative symptoms on the total PANSS score.

Secondary outcome measures
1. Three-month change in the PANSS subscales
2. Cognitive symptoms
3. Immunological parameters (g-interferon, interleukin 4 [IL-4], interleukin 6 [IL-6] and interleukin 12 [IL-12])

Overall study start date
01/01/2004

Completion date
01/09/2007

Eligibility

Key inclusion criteria
1. Schizophrenia, schizo-affective disorder, schizofreniform disorder according to Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV) (for a maximum of 5 years) (as of 03/06/2008 this has been updated to a maximum of 10 years)
2. Aged 18 - 55 years
3. Stable
4. Minimum score of 60 on Positive and Negative Syndrome Scale (PANSS)
5. Minimum 2 x a score of minimum 4 on PANSS

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
80

Key exclusion criteria
1. No contra-indication for acetylsalicylic acid
2. No hypersensitivity to acetylsalicylic acid or pantoprazole
3. No significant somatic illness

4. No chronic use of a non-steroidal anti-inflammatory drug (NSAID)
5. No use of corticosteroids
6. Not pregnant
7. No drug dependency
8. Informed consent obtained

Date of first enrolment
01/01/2004

Date of final enrolment
01/09/2007

Locations

Countries of recruitment
Netherlands

Study participating centre
Department of Epidemiology and Bioinformatics
Groningen
Netherlands
9700 AR

Sponsor information

Organisation
University Medical Centre Utrecht (UMCU) (Netherlands)

Sponsor details
P.O. Box 85500
Utrecht
Netherlands
3508 GA

Sponsor type
University/education

Website
http://www.umcutrecht.nl/zorg/

ROR
https://ror.org/04pp8hn57

Funder(s)

Funder type
Research organisation

Funder Name
Stanley Medical Research Institute (USA)

Alternative Name(s)
The Stanley Medical Research Institute, SMRI

Funding Body Type
Private sector organisation

Funding Body Subtype
Research institutes and centers

Location
United States of America

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	23/10/2006		Yes	No
Results article	results	01/05/2010		Yes	No