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A randomised study of sulindac and epalrestat in diabetic retinopathy

Submission date	Recruitment status	[ ] Prospectively registered
11/10/2006	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
12/10/2006	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
16/10/2009	Eye Diseases	[ ] 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
N/A

Study information

Scientific Title

Acronym
RSSEDR

Study objectives
The primary purpose is to evaluate the effects of long term treatment with sulindac and epalrestat in diabetic retinopathy.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Institutional Review Board of Asama General Hospital, date of Approval 01/08/1997 (reference number: AGH 97-01).

Study design
Interventional randomised single-blind uncontrolled parallel-assignment trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Diabetic Retinopathy

Interventions
1. The sulindac group: patients took 100 mg of sulindac twice a day
2. The epalrestat group: patients took 50 mg of epalrestat three times a day
3. The control group: patients took no additional medications

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Sulindac, epalrestat

Primary outcome measure
1. Seven-field stereoscopic retinal photography at baseline, and yearly intervals
2. Endpoint if they were diagnosed with proliferative diabetic retinopathy

Secondary outcome measures
1. Glycosylated Hemoglobin (GHb) values determine at monthly intervals
2. Remain on their medications for three years
3. Endpoint if exhibited a dipstick proteinuria of more than or equal to 1+

Overall study start date
01/10/1997

Completion date
31/10/2000

Eligibility

Key inclusion criteria
1. Clinical diagnosis of type two diabetes
2. Age 20 years or older
3. Patient consent

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
48

Key exclusion criteria
1. Having diabetes for less than five years
2. HbA1c less than 8.0%
3. Taking other medications except for oral hypoglycemic agents or insulin injections
4. Hypertension
5. Inability to understands the implications of the the protocol

Date of first enrolment
01/10/1997

Date of final enrolment
31/10/2000

Locations

Countries of recruitment
Japan

Study participating centre
Department of Molecular Oncology
Matsumoto
Japan
390-8621

Sponsor information

Organisation
Asama General Hospital (Japan)

Sponsor details
1862-1
Iwamurada
Saku
Japan
385-8558
+81 267 67 2295
asamaghp@avis.ne.jp

Sponsor type
Hospital/treatment centre

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Internally funded by participant centre, Asama General Hospital (Japan)

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