

# A randomised study of sulindac and epalrestat in diabetic retinopathy

<b>Submission date</b> 11/10/2006	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 12/10/2006	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 16/10/2009	<b>Condition category</b> Eye Diseases	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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

**Protocol serial number**  
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

### **Study type(s)**

Treatment

### **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(s)**

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

### **Key secondary outcome(s)**

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+

### **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

## Healthy volunteers allowed

No

## Age group

Adult

## Sex

All

## 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 understand the implications of 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)

**Funder(s)****Funder type**

Hospital/treatment centre

**Funder Name**

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

**Results and Publications****Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration