

The Efficacy of Self-MONitoring of blood glucose in patients with type two diabetes mellitus

Submission date
08/01/2007

Recruitment status
No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date
26/02/2007

Overall study status
Completed

☐ Statistical analysis plan

☒ Results

Last Edited
21/04/2008

Condition category
Nutritional, Metabolic, Endocrine

☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

Protocol serial number

RRG5.7

Study information

Scientific Title

Acronym

ESMON

Study objectives

Self blood glucose monitoring is not associated with benefit in terms of improved glycaemic control or psychological indices.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from:

1. University of Ulster Ethics Committee on the 17th August 2001 (ref: 01/29)
2. Altnagelvin Hospitals Health and Social Services Trust on the 14th June 2000

Primary study design

Interventional

Study design

Prospective randomised controlled trial

Study type(s)

Screening

Health condition(s) or problem(s) studied

Type two diabetes mellitus

Interventions

Self monitoring of blood glucose versus non-monitoring.

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

1. Between-group differences in glycaemic control (HbA1c)
2. Between-group differences in psychological indices
3. Between-group differences in reported hypoglycaemia

Key secondary outcome(s)

1. Between-group differences in body mass index (BMI)
2. Between-group differences in oral hypoglycaemic drug usage
3. Longitudinal within-group changes in HbA1c, BMI and psychological indices

Completion date

01/01/2006

Eligibility

Key inclusion criteria

1. Patients with newly diagnosed type two diabetes
2. Aged less than 70 years old

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

1. Secondary diabetes
2. Insulin use
3. Previous monitoring
4. Pregnancy
5. Previous malignancy
6. Major illness within 6 months (including major surgery, myocardial infarction (MI), acute coronary syndrome, stroke, acute limb ischaemia)
7. Liver disease
8. Creatinine > 150 µmol/L
9. Proteinuria > 0.5 g/ 24 h
10. Chronic use of oral steroids
11. Alcohol abuse

Date of first enrolment

01/12/2000

Date of final enrolment

01/01/2006

Locations**Countries of recruitment**

United Kingdom

Northern Ireland

Study participating centre**School of Nursing**

Coleraine

United Kingdom

BT52 1SA

Sponsor information

Organisation

University of Ulster (UK)

ROR

<https://ror.org/01yp9g959>

Funder(s)

Funder type

Government

Funder Name

Northern Ireland Department of Health, Research and Development Office (UK)

Results and Publications

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?
Results article	Results	24/05/2008		Yes	No