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

Submission date	Recruitment status	Prospectively registered		
08/01/2007	No longer recruiting	☐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
26/02/2007	Completed	[X] Results		
Last Edited	Condition category	[] Individual participant data		
21/04/2008	Nutritional, Metabolic, Endocrine			

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Prof Vivien Coates

Contact details

School of Nursing
University of Ulster
Coleraine campus
Coleraine
United Kingdom
BT52 1SA
ve.coates@ulster.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Study design

Prospective randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Screening

Participant information sheet

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 measure

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

Secondary outcome measures

- 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

Overall study start date

01/12/2000

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

Age group

Adult

Sex

Both

Target number of participants

200

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

Northern Ireland

United Kingdom

Study participating centre School of Nursing

Coleraine United Kingdom BT52 1SA

Sponsor information

Organisation

University of Ulster (UK)

Sponsor details

c/o Prof Vivien Coates School of Nursing Coleraine campus Coleraine Northern Ireland United Kingdom BT52 1SA ve.coates@ulster.ac.uk

Sponsor type

University/education

Website

http://www.ulster.ac.uk

ROR

https://ror.org/01yp9g959

Funder(s)

Funder type

Funder Name

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

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?
Results article	Results	24/05/2008		Yes	No