

Delivering Early Care In Diabetes Evaluation (DECIDE): To assess hospital versus home management at diagnosis in childhood type 1 diabetes - a comparison of psychological, social, physical and economic outcomes

Submission date 03/08/2007	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 09/11/2007	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 21/05/2021	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Lesley Lowes

Contact details
Department Of Child Health
University Hospital Of Wales
Heath Park
Cardiff
United Kingdom
CF14 4XW

Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title

Delivering Early Care In Diabetes Evaluation (DECIDE): To assess hospital versus home management at diagnosis in childhood type 1 diabetes - a comparison of psychological, social, physical and economic outcomes

Acronym

DECIDE

Study objectives

To determine whether, in children with newly diagnosed diabetes who are not acutely unwell, it is better to admit to hospital for initiation of insulin treatment and education of child and family, or whether results would be better if initial management was provided at home.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Multi-centre Research Ethics Committee for Wales, 26/10/2007, ref: 07/MRE09/59

Study design

Multi-centre randomised controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Type 1 diabetes

Interventions

Patients will be randomised to either:

1. Home management
2. Hospital management

Patients and their parents will be randomised on the day of diagnosis to receive their diabetes treatment from home or from hospital. Patients in the Hospital Management Group will be admitted for a minimum of three nights (receiving at least six supervised injections while hospitalised). Patients in the Home Management Group will be discharged home on day of diagnosis and treatment and support will be delivered at home for a minimum of three days (at least six supervised injections). All patients will receive the same care and at their 1, 12 and 24 month clinic visits follow-up data will be collected and when the patients HbA1c is being tested, extra blood will be taken to be sent off for HbA1c analysis at a central laboratory. At 1, 12 and 24 months post diagnosis patients aged greater than or equal to 8 years old and all parents will be asked to complete a questionnaire to assess psychological, social, physical or economic outcomes of home or hospital management. Children with type 1 diabetes have traditionally been hospitalised at diagnosis but are increasingly starting treatment at home. There is no high-quality evidence regarding psychological, social, physical or economic outcomes of home or hospital management.

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

Glycaemic control (HbA1c) over the 2 years post diagnosis.

Measurements will be taken at 0, 1, 12 and 24 months.

Key secondary outcome(s)

1. Clinical: growth (height, weight, body mass index [BMI]) and adverse events (e.g. severe hypoglycaemia)
2. Patient: quality of life, coping with diabetes, diabetes knowledge, satisfaction and time off school
3. Parent: anxiety, coping with diabetes, diabetes knowledge, satisfaction and time off work
4. Health professionals: experience of both approaches to care
5. Health resource usage: hospitalisation, home and clinic visits

Measurements will be taken at 0, 1, 12 and 24 months.

Completion date

01/01/2012

Eligibility**Key inclusion criteria**

1. Children aged 0 - 17 years old
2. Newly diagnosed type 1 diabetes (using recognised standard diagnostic criteria) who are clinically well (pH greater than 7.29) at presentation
3. Written informed consent given by parent(s)/carer/child and assent from child
4. Able to fill out study material (all parents and children aged greater than or equal to 8 years old)

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Child

Upper age limit

17 years

Sex

All

Total final enrolment

203

Key exclusion criteria

1. Children with a coexisting chronic disorder (e.g., cystic fibrosis) which will impact significantly on blood glucose control
2. Children with type 2 diabetes
3. Children with Maturity Onset Diabetes of the Young (MODY)
4. Children with an uncertain diagnosis
5. Children who are under the care of the local authority
6. Children whose home circumstances are assessed as being unsuitable for home management
7. Children who require hospitalisation for reasons other than their diagnosis

Date of first enrolment

01/01/2008

Date of final enrolment

01/01/2012

Locations**Countries of recruitment**

United Kingdom

Wales

Study participating centre

Department Of Child Health

Cardiff

United Kingdom

CF14 4XW

Sponsor information**Organisation**

Cardiff University (UK)

ROR

<https://ror.org/03kk7td41>

Funder(s)

Funder type

Charity

Funder Name

Diabetes UK (UK), ref: BDA:RD06/0003353

Alternative Name(s)

The British Diabetic Association, DIABETES UK LIMITED, British Diabetic Association

Funding Body Type

Private sector organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location

United Kingdom

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	01/01/2016		Yes	No
Results article	results	03/12/2019	05/11/2020	Yes	No
Results article	cost-effectiveness results	19/05/2021	21/05/2021	Yes	No
Protocol article	protocol	19/01/2011		Yes	No