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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	Recruitment status	[X] Prospectively registered
03/08/2007	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
09/11/2007	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
21/05/2021	Nutritional, Metabolic, Endocrine	

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
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Type 1 diabetes

Interventions

Patients will be randomised to either:
1. Home management
2. Hospital managment

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

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

Secondary outcome measures
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.

Overall study start date
01/01/2008

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

Age group
Child

Upper age limit
17 Years

Sex
Both

Target number of participants
240

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)

Sponsor details
30 - 36 Newport Road
Cardiff
Wales
United Kingdom
CF24 0DE

Sponsor type
University/education

Website
http://www.cf.ac.uk

ROR
https://ror.org/03kk7td41

Funder(s)

Funder type
Charity

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

Alternative Name(s)
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

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?
Protocol article	protocol	19/01/2011		Yes	No
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