

# 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

<b>Submission date</b> 03/08/2007	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 09/11/2007	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 21/05/2021	<b>Condition category</b> 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**  
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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 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 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?
<a href="#">Protocol article</a>	protocol	19/01/2011		Yes	No
<a href="#">Results article</a>	results	01/01/2016		Yes	No
<a href="#">Results article</a>	results	03/12/2019	05/11/2020	Yes	No
<a href="#">Results article</a>	cost-effectiveness results	19/05/2021	21/05/2021	Yes	No