

PDC – Type 2 Diabetes in Children

NIHR BioResource – Rare Diseases study project

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Summary

Type 2 Diabetes (T2D) has emerged in children in the UK in the last 20 years, probably related to the general rise in population obesity. It is thought there are less than 1,000 children and young people (aged up to 18 years) affected in the UK.



Prof. Tim Barrett, PDC project Lead

Many of these have a family history of T2D in a parent, suggesting they may be genetically enriched for this multifactorial disease; and the possibility of maternal diabetes in pregnancy influencing development of diabetes in children.

T2D in children appears to be more aggressive, and progresses faster, than T2D in adults. There is significant industry interest in recruiting children to studies of new treatments. The overall objective is to characterise a cohort of children and young people with T2D. This will include baseline and repeat assessments of the growth, cardiovascular, metabolic and psychological status children with T2D in order to:

1. Describe the natural history of T2D and complications in a multi-ethnic cohort of UK children with the disease;
2. Undertake academic investigator-led studies into the pathophysiology of the disease;
3. Support recruitment to industry studies of new treatments.

Recruitment Criteria

Inclusion

- Patients aged 5-18 completed years
- Have diabetes according to the ADA criteria (laboratory determinations of fasting glucose ≥ 7.0 mmol/l, or two-hour OGTT glucose ≥ 11.1 mmol/l) and documented and confirmed in the medical record. For asymptomatic children diagnosed with diabetes with a normal fasting glucose but an elevated two-hour glucose during an OGTT, the HbA1c must be $\geq 6\%$. Children previously diagnosed with diabetes and laboratory

determination of HbA1c $\geq 8\%$ at the time of diagnosis will be accepted as surrogate evidence of eligibility, if there was no documented laboratory determination of serum glucose.

- Have a suspected diagnosis of T2D made by his/her local general practitioner or paediatrician.
- Have BMI $\geq 85^{\text{th}}$ centile for age and sex according to the Child Growth Foundation BMI charts documented at time of diagnosis or at screening.

Exclusion

- Genetically confirmed monogenic diabetes (e.g. MODY or diabetes syndrome) or other syndrome associated with diabetes (e.g. Downs, Prader-Willi).
- Any secondary diabetes e.g. cystic fibrosis-related, transplant-related or thalassaemia-related diabetes
- Any existing evidence of pancreatic autoimmunity (any of anti-GAD65, anti-ICA512. Insulin antibodies (IAA) may be positive if the patient has had previous insulin treatment).
- Other significant organ system illness or condition (including psychiatric or developmental disorder) that would prevent participation in the opinion of the investigator.