

Type 1 diabetes monitoring and ophthalmic complications in children in the Democratic République of Congo

Submission date 18/04/2024	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 16/05/2024	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 16/05/2024	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

In the Democratic Republic of Congo (DRC), it's common for children with Type 1 diabetes to develop a condition called diabetic retinopathy (DR), which affects the eyes. However, we've found that by educating patients about managing their condition and using continuous glucose monitoring systems (CGM) that measure glucose levels under the skin, we can decrease the occurrence of DR in these children in the DRC.

Who can participate?

This study includes children with Type 1 diabetes, with or without DR, from different diabetes clinics in Kinshasa managed by the Diocesan Medical Works Office (BDOM).

What does the study involve?

This research compares various aspects of health, including biological markers, eye health, and overall physical well-being, as well as the effectiveness of managing Type 1 diabetes and the advancement of diabetic retinopathy (DR) in two groups of children. One group uses a continuous glucose monitoring system (CGM), specifically the Dexcom one, while the other group monitors their blood glucose levels through self-testing.

What are the possible benefits and risks of participating?

During the study, all necessary monitoring equipment will be provided. They also get free medical tests and eye check-ups. They will receive guidance on managing their condition through patient therapeutic education.

Where is the study run from?

University Clinic of Kinshasa (Democratic Republic of Congo)

When is the study starting and how long is it expected to run for?

October 2023 to December 2025

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
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Additional identifiers**EudraCT/CTIS number**

Nil known

IRAS number**ClinicalTrials.gov number**

Nil known

Secondary identifying numbers

STUDY DT1/RD3

Study information**Scientific Title**

Type 1 diabetes in children and diabetic retinopathy in the Congolese environment: clinical, therapeutic and preventive approach

Study objectives

The use of continuous glucose monitoring (CGM) sensors can improve diabetes management and the progression of microangiopathic complications (diabetic retinopathy) in children with type 1 diabetes in the city of Kinshasa in the Democratic Republic of the Congo

Ethics approval required

Ethics approval required

Ethics approval(s)

Approved 25/10/2023, National Health Ethics committee of Democratic Republic of Congo (PNMLS Building, local 5 Kasa vubu, Kinshasa, -, Congo, Democratic Republic; +243 99 84 19 816; fel1munday@yahoo.fr), ref: 490/CNES/BN/PMMF/2023

Study design

Multicenter interventional randomized control trial

Primary study design

Interventional

Secondary study design

Randomised parallel trial

Study setting(s)

Care home, Hospital, Laboratory, University/medical school/dental school

Study type(s)

Diagnostic, Prevention, Treatment, Efficacy

Participant information sheet

No participant information sheet available

Health condition(s) or problem(s) studied

Type 1 diabetes, diabetic retinopathy

Interventions

We sampled type 1 diabetic patients aged 5 to 18 years with early-stage diabetic retinopathy. After 1:3 randomization, two groups were formed: group 1 used continuous glucose monitoring (CGM) with Dexcom one sensor for glycemic control, measuring interstitial glucose, while group 2 utilized fingerstick glycemic control, measuring capillary glucose. Biological parameters (HbA1c and microalbuminuria) were followed up at months 1, 3, 6, 9, and 12, and diabetic retinopathy stage was assessed at months 1 and 12.

Intervention Type

Device

Pharmaceutical study type(s)

Not Applicable

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Dexcom ONE sensor

Primary outcome measure

1. Hb1Ac levels measured using the Siemens DCA VANTAGE analyzer at months 1, 3, 6, 9, and 12
2. Microalbuminuria measured using the Siemens DCA VANTAGE analyzer at months 1, 3, 6, 9, and 12
3. Stages of diabetic retinopathy measured using the 2016 standards for screening and surveillance of ocular complications in people with diabetes at months 1 and 12

Secondary outcome measures

1. Glycemic average measured using the following standard formula: $\text{Hb1ac (in \%)} \times 1.59 - 2.59$ at months 1, 3, 6, 9, and 12

2. Time in range (TIR) measured using a Dexcom ONE MCG sensor at months 1, 3, 6, 9, and 12
3. Body mass index (BMI) calculated by dividing weight in kg by height in cm squared at months 1, 3, 6, 9, and 12

Overall study start date

25/10/2023

Completion date

31/12/2025

Eligibility

Key inclusion criteria

1. Children under 18 years of age, of both sexes, followed in the six diabetic clinics in Kinshasa
2. Known diabetic with diabetic retinopathy
3. No-sickle cell children
4. Informed consent from parents

Participant type(s)

Patient

Age group

Child

Lower age limit

5 Years

Upper age limit

18 Years

Sex

Both

Target number of participants

1000

Key exclusion criteria

1. Age over 18 years
2. Non-type1 diabetes mellitus
3. Non-consent

Date of first enrolment

04/03/2024

Date of final enrolment

30/12/2024

Locations

Countries of recruitment

Congo, Democratic Republic

Study participating centre

The six diabetic clinics of the city of Kinshasa (RDC)

Kinshasa

Congo, Democratic Republic

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Sponsor information

Organisation

University Clinic of Kinshasa

Sponsor details

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Sponsor type

University/education

Funder(s)

Funder type

Other

Funder Name

Investigator initiated and funded

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal

Intention to publish date

30/12/2025

Individual participant data (IPD) sharing plan

Data sharing plans for the ongoing study are currently unknown and will be available at later date

IPD sharing plan summary

Data sharing statement to be made available at a later date