



## **Congenital CMV infections in Switzerland**

### **Principle Investigator:**

Prof. Klara Posfay-Barbe  
Head of paediatric infectious diseases  
University Hospitals of Geneva  
6, rue Willy-Donzé  
1211 Geneva

Phone: +41 22 372 54 62  
Fax: +41 22 372 54 85  
Email: klara.posfaybarbe@hcuge.ch

### **Study rationale**

CMV is the most common cause of congenital infections with a prevalence estimated between 0.6 and 0.7 % of live births in developed countries. Of these children, 10–15 % will be symptomatic at birth and 10–15 % of asymptomatic children will nevertheless develop serious complications later on (mostly hearing loss and visual impairment). To this date, no epidemiological data concerning congenital CMV in Switzerland is available, although more knowledge would probably improve recommendations for screening and care. Other national PSUs are currently doing a similar study.

### **Primary objective**

- Measure the prevalence of congenital CMV (cCMV) in hospitalized or symptomatic children < 12 months of age in Switzerland.

### **Secondary objectives**

- Establish a national epidemiological surveillance registry on cCMV in Switzerland.
- Follow the evolution of the prevalence of cCMV in Switzerland.
- Determine the impact of cCMV on the psychomotor development.
- Evaluate the necessity/ possibility to implement systematic screening of cCMV at birth
- If possible, identify sociodemographic factors associated with cCMV in Switzerland.

Our hypothesis is that the prevalence of cCMV is similar to that of other developed countries, but that it could vary according to sociodemographic factors.

### **Study description**

Observational, multicentric, anonymized study of all newborns alive at birth in Switzerland, using the *SPSU* network. The study period should cover 5 years (spring 2016–spring 2023).

Two step approach: 1) declaration of cases through the monthly *SPSU* card; 2) filling of a specific, individualized, anonymized case-report form (see attached) by physician in charge, with a follow-up at one year.

Inclusion criteria:

- 1) Confirmed cCMV (diagnosis in or ex-utero before 3 weeks of life by PCR, direct isolation or antigen of CMV
- 2) Suspected cCMV: positive IgM, or isolated CMV after 3 weeks of life but before one year of life and with symptoms compatible with cCMV (prematurity, microcephaly, intracranial calcifications, etc).

Exclusion criteria:

- 1) Children with post-natally acquired CMV
- 2) Still-birth.

**Start and duration:**

April 2016–March 2023

**Expected sample size**

With a prevalence of cCMV at birth of 0.64% [95%IC: 0.60–0.69%], for 80'290 births in Switzerland in 2010, the measuring precision is 0.055 % for 514 newborns affected by cCMV per year. Knowing that 10 %–15 % will be symptomatic at birth and 10–15% later, we expect between 51–77 patients affected at birth and 51–77 patients during the first months or years of life for a total of 103–154 patients. Extrapolated to an annual birthrate of 100'000 individuals, the expected number of children with sequelae is 127–192 patients/100'000 births/year in Switzerland.

*SPSU*-Vorsitzender: Prof. Dr. med. C. Rudin, Leitender Arzt, UKBB, Spitalstrasse 33, 4056 Basel  
*SPSU*-Sekretariat: Bundesamt für Gesundheit, Abt. Übertragbare Krankheiten, 3003 Bern  
Tel. 058 463 02 97 oder 058 463 87 06, Fax 058 463 87 95,  
e-Mail: [spsu@bag.admin.ch](mailto:spsu@bag.admin.ch) [www.bag.admin.ch/k\\_m\\_meldesystem](http://www.bag.admin.ch/k_m_meldesystem)