

SEVEN-YEAR FOLLOW-UP OF THE IMMUNE RESPONSE AFTER ONE OR TWO DOSES OF INACTIVATED HEPATITIS A VACCINE GIVEN AT 1 YEAR OF AGE IN THE MENDOZA PROVINCE OF ARGENTINA

Carlos Espul¹, Laura Benedetti², Mariela Linares², Hector Cuello³, Ivana Lo Castro³, Yaël Thollot⁴, Anvar Rassouli⁴

¹Ministerio de Salud/Hospital Central de Mendoza, Mendoza, Argentina; ²Ministerio de Salud, Mendoza, Argentina; ³Sección Virología, Hospital Central de Mendoza, Mendoza, Argentina; ⁴Sanofi Pasteur, Lyon, France

BACKGROUND

- Argentina has diverse environmental and socio-economic conditions, and diverse rates of hepatitis A (HA) virus (HAV) endemicity.
- Universal, single-dose HA vaccination at 1 year of age was introduced in the region of Mendoza in 2004, and throughout Argentina in 2005.
- In middle-income countries and regions with transitional HAV prevalence, such as Mendoza, where circulation of wild HAV is still observed, a single-dose vaccination strategy may be effective, but should be validated versus a complete vaccination course (one primary vaccine dose followed by one booster vaccination).
- In this ongoing study we are evaluating the long-term anti HAV immune responses after one or two vaccine doses given at 11 to 23 months of age in a cohort in Mendoza
- Results to Year 5 (Y5) have been reported previously (1) Here we present results seven years after vaccination.

METHODS

- Monocentre, descriptive, prospective, non-interventional study in children who received routine HA vaccination one year previously, at age 11-23 months.
- The vaccination routinely used in Mendoza is the licensed, inactivated HA vaccine (Avaxim® 80U pediatric, Sanofi Pasteur). One or two doses were given.
- Anti-HAV antibodies were quantified annually up to Y5, and at Y7.
- Children with titers below the seroprotection threshold* received a routine booster dose of the same HA vaccine outside of the study, but were not withdrawn from the study.
- The study evaluated only immunogenicity; no safety data were collected.
- Study was performed according to ICH Good Clinical Practices, and all relevant ethical and regulatory requirements.

* Defined as anti-HAV antibody concentration of ≥ 10 mIU/mL in a microparticle enzyme immunoassay up to Y5, or ≥ 3 mIU/mL in an electrochemiluminescence immunoassay at Y7

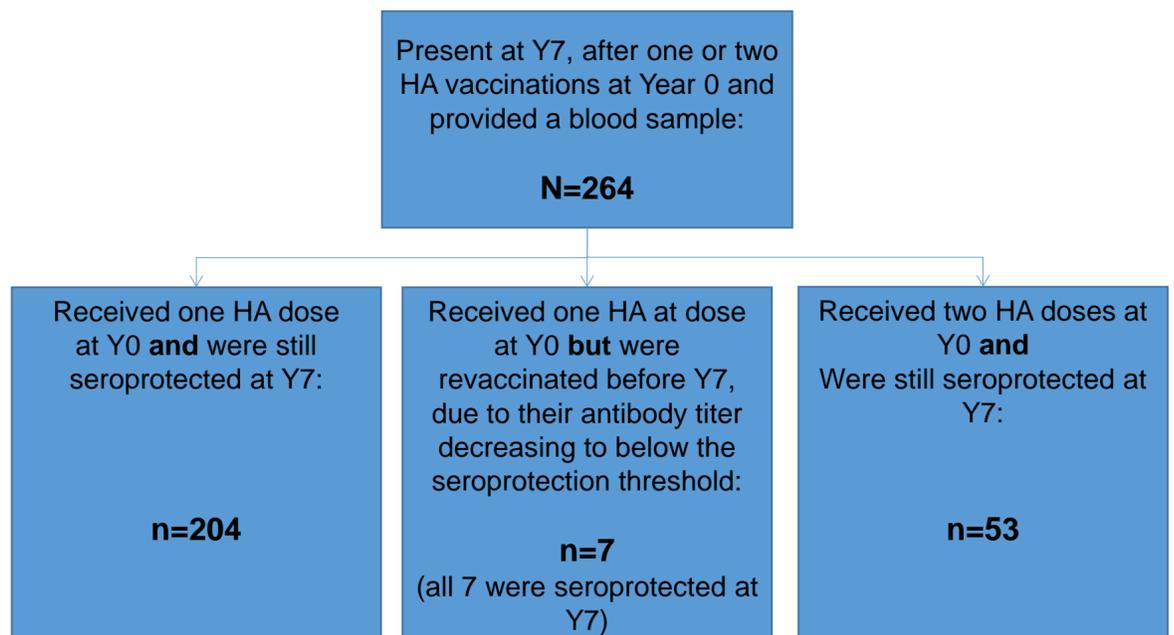
RESULTS

STUDY POPULATION

- Of 546 toddlers initially included, 264 were present at Y7 and provided a blood sample.
- The proportion of male:female was 49.6%:50.4% at baseline (Y1), and 50.5%:49.5% at Y7.
- At baseline mean age (\pm SD) was 28.5 ± 2.44 months

ANTIBODY PERSISTENCE AT YEAR 7

- Of 211 toddlers vaccinated at Y0 with one dose of HA, and for whom Y7 data are available, 204 (97%) remained seroprotected without the need for a booster dose.



SOCIO-ECONOMIC FACTORS AT Y7

- The proportion was mainly urban (81%) or suburban (16%) dwelling, and less than 2% were rural dwelling.
- All participants had a toilet at home, with 98% of these being indoors; 99% had access to potable water; and 92% had access to a sewage network.
- All participants were in daycare 5 days/week, most of whom (>85%) were cared for in groups of at least 20
- 97% of fathers, and 55% of mothers had working activity.

REFERENCES

- (1) Espul et al. Five-year follow-up of immune response after one or two doses of inactivated hepatitis A vaccine given at 1 year of age in the Mendoza Province of Argentina. *J Viral Hepat* 2014;22(4):453-458.

The work presented in this poster has now been accepted for publication:

Espul et al. Seven-year follow-up of the immune response after one or two doses of inactivated hepatitis A vaccine given at 1 year of age in the Mendoza Province of Argentina. *Hum Vaccin Immunother* 2017 (in press)

CONFLICTS OF INTEREST / DISCLOSURES

Funding: Sanofi Pasteur
CE, LB, ML, HC, and ILC declare no conflicts of interest; YT and AR are employed by Sanofi Pasteur.

CONCLUSIONS

One or two primary doses of this HA vaccine in toddlers result in very good persistence of anti-HAV up to 7 years post-first vaccination.

Contact

Carlos Espul carlos.espul@gmail.com)
Ministerio de Salud / Hospital Central de Mendoza, Mendoza, Argentina