vax-ID

a newly developed medical device for intradermal administration of vaccines by novosanis

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Intradermal vaccination

Intradermal vaccination, i.e. delivery of vaccines in the dermal layer of the skin, has many advantages, including
- dose-sparing properties
- improved immune response
- improved safety
- simpler logistics of delivery

Despite these advantages, devices to accurately deliver vaccines in the dermal layer of the skin are scarce. Medical scientists, product developers and economists of the University of Antwerp (UA) and Artesis University College joined forces with VOXDALE BVBA, a design and engineering SME based in Antwerp, to develop a device that allows for intradermal administration of substances, including vaccine antigens.

Multidisciplinary approach

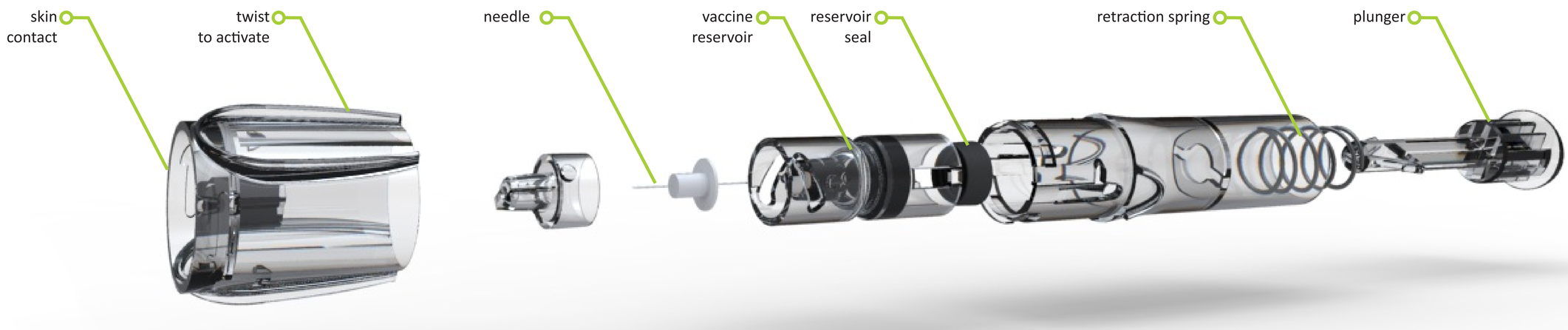
The multidisciplinary approach, combined with a distinct university-industry collaboration led to the development of a prototype device VAX-ID. Additionally, a grant was provided by the Belgian Industrial Research & Development Fund (BiR&D). The latter provided funding for 3 master theses (Applied Economics, Nursing and Midwifery, Product Development) supporting the development of a prototype device, development of a business model and clinical evaluation of the device in healthy volunteers.

Advantages

The VAX-ID device meets preset technological challenging requirements in terms of safety, waste management, ease of use, use by untrained medical staff, suitability for use in elderly and children, use at anatomic sites other than the deltoid region, next to assembly and production requirements.

A worldwide patent application (PCT) has been filed for VAX-ID

The VAX-ID device



1 twist to activate
needle penetrates reservoir

2 make skin contact

3 push plunger to administer
plunger empties reservoir

4 needle auto-retracts
needle-stick safe

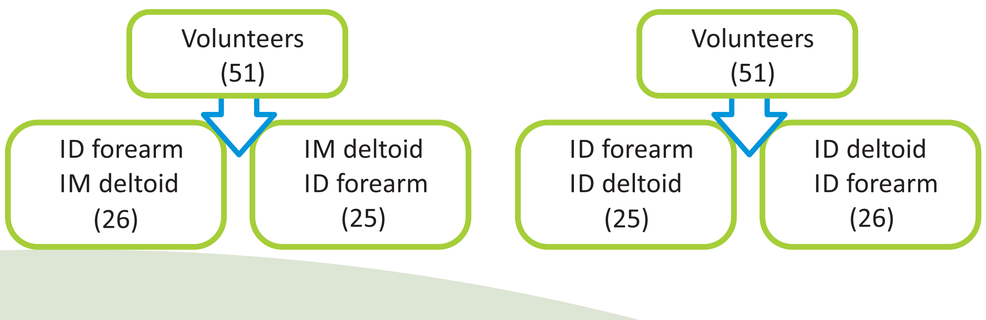
5 dispose of device
one-time use only

Clinical trials

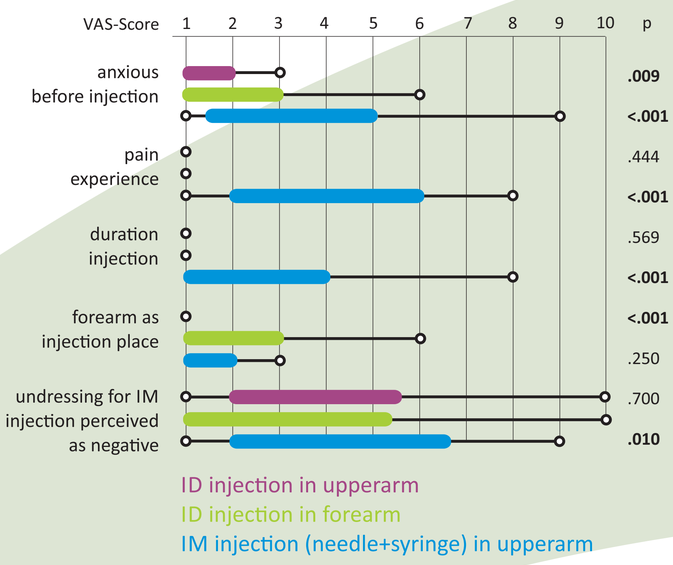
A phase 1 clinical trial was performed in 102 healthy volunteers aged 18-65 to allow evaluation of the usability and acceptability of the VAX-ID device for injections in the deltoid region and the forearm. The volunteers were injected with either 0.1 cc intradermal (ID) or 0.5 cc intramuscular (IM) of saline (0.9%) solution.

All volunteers were asked to fill a questionnaire the day of the survey on acceptability of the VAX-ID device and were also asked to complete a 5-day dairy for assessment of local and systemic reactions.
The ID injection using VAX-ID was perceived as non-painful by all vaccinees and few local reactions (only redness) were reported after injection.

Set-up phase 1 study (102 healthy volunteers)



Outcome VAS-scores per injection

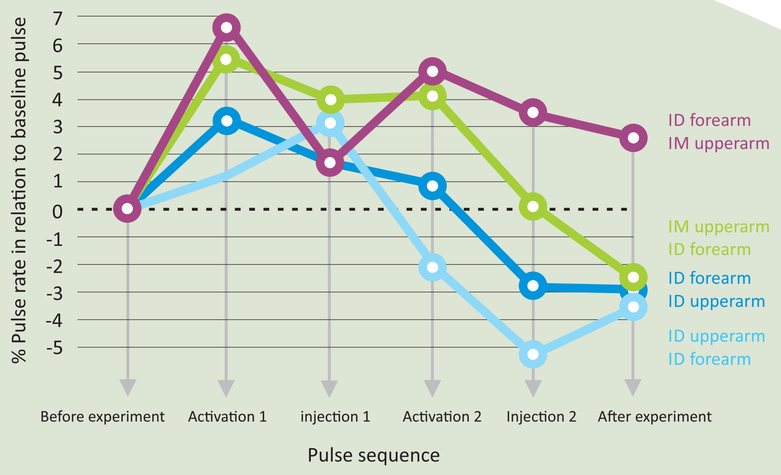


Local reactions after one day for each type of injection

	Mean (SD)	p*	Mean (SD)	
Pain	1.07 (0.30)	.785 **< .001**	1.12 (0.44) 1.64 (1.01)	ID IM
Redness	1.19 (0.49)	**.031** .109	1.10 (0.37) 1.26 (0.64)	ID IM
Redness in mm	0.26 (1.03)	.261 .211	0.14 (0.50) 0.93 (3.06)	ID IM
Swelling	1.01 (010)	- .569	1.00 (0.00) 1.06 (0.25)	ID IM
Swelling in mm	0	- .197	0 0.19 (0.83)	ID IM
Ecchymosis	1.02 (0.14)	- .710	1.00 (0.00) 1.13 (0.54)	ID IM
Ecchymosis in mm	0	- .162	0 0.30 (1.16)	ID IM
Hardening/induration	1.03 (0.23)	.322 .323	1.02 (0.14) 1.19 (0.54)	ID IM
Hardening in mm	0.01 (0.10)	.322 .083	0.08 (0.57) 0.19 (0.54)	ID IM

* Paired Samples T-Test

Calibrated pulse rate in relation to baseline pulse



ID injections using VAX-ID were experienced as less painful and less long-lasting compared to IM injections using needle and syringe. The volunteers were less scared of the VAX-ID device than of seeing needle and syringe.

Importantly, there were no significant differences with regard to systemic and local reactions, except for the more pronounced pain perception at the injection site for IM injections and a higher degree of redness after ID injections.

When investigating the pulse rate per minute, independent of the injection method, the first activation of the device led to an increase in pulse rate. Interestingly, when the second injection was IM after first receiving an ID injection, the pulse rate increased more compared to ID injection after IM injection.

Novosanis, newly founded UA spin-off company

In conclusion, after a very successful first phase this innovative intradermal injection device VAX-ID can now be assessed for clinical immunogenicity and safety with vaccine antigen in larger cohorts of adults, children and elderly. A newly established UA spin-off company, Novosanis NV, will be responsible for commercialization and marketing of VAX-ID. Additionally, further valorization opportunities, including licensing deals are currently being explored.

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