vax-ID

Assessment of acceptability and usability of new delivery prototype device for intradermal vaccination in healthy subjects

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Background

The objective of the study was to assess the acceptability and usability of a newly developed intradermal prototype device, VAX-ID, in healthy subjects.

Materials & Methods

In April 2012 a clinical study was conducted in healthy subjects aged 18 to 65 years. To compare injection site and route of administration, subjects were allocated to four subgroups, either receiving subsequently twice an intradermal(ID) injection (one in the forearm and one in the deltoid) or an ID (forearm) and intramuscular(IM) (deltoid) injection. All injections contained saline solution. Acceptability was assessed with a subjects' questionnaire and a daily electronic diary for 5 days. Usability was assessed with a vaccinators' questionnaire and an expert panel. A 10-point Visual Analogue Scale was used to score several statements on usability and acceptability.

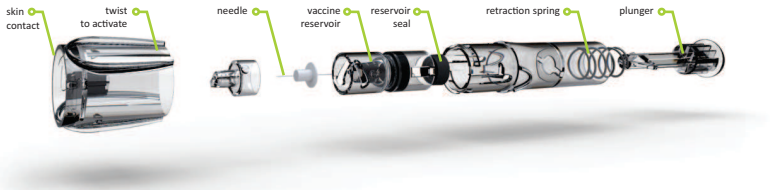
Results

A total of 102 healthy subjects were enrolled in the study (age:19-63 years). No statistically significant differences were seen in demographic characteristics between the ID and IM groups. Anxiety before injection, pain during injection and duration of injection were rated significantly lower for ID compared to IM ($p<0.001$). One day after the injections, only redness was reported more often after ID injection in the forearm versus ID in the deltoid; pain at injection site was reported significantly more often after IM versus ID injection ($p<0.001$). The new VAX-ID prototype device was found easy to handle, easy to use and safe.

Conclusion

The VAX-ID prototype device was shown to have a high degree of acceptability and usability. Further studies with VAX-ID will be set-up including a Phase I vaccine antigen study to assess immunogenicity and further document safety.

Patent pending: PCT/EP2013/057990



1 twist to activate — *needle penetrates reservoir*

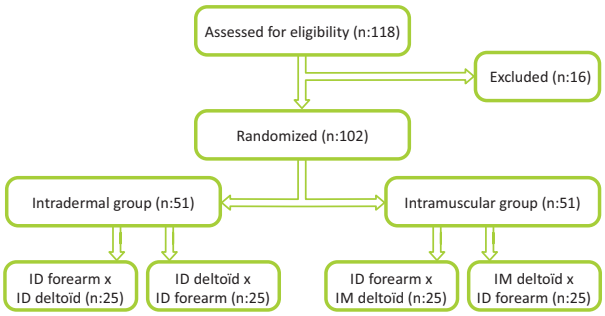
2 make skin contact

3 push plunger to administer — *plunger empties reservoir*

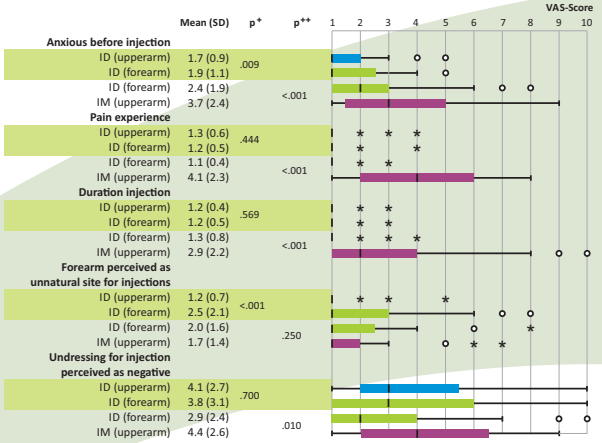
4 needle auto-retracts — *needle-stick safe*

5 dispose of device — *one-time use only*

Set-up phase 1 study (118 volunteers)



Outcome 10-point Visual Analogue Scale per injection (n:102)



	Mean (SD)	p+	p++
Anxious before injection			
ID (upperarm)	1.7 (0.9)	.009	
ID (forearm)	1.9 (1.1)		
ID (forearm)	2.4 (1.9)	<.001	
IM (upperarm)	3.7 (2.4)		
Pain experience			
ID (upperarm)	1.3 (0.6)	.444	
ID (forearm)	1.2 (0.5)		
ID (forearm)	1.1 (0.4)	<.001	
IM (upperarm)	4.1 (2.3)		
Duration injection			
ID (upperarm)	1.2 (0.4)	.569	
ID (forearm)	1.2 (0.5)		
ID (forearm)	1.3 (0.8)	<.001	
IM (upperarm)	2.9 (2.2)		
Forearm perceived as unnatural site for injections			
ID (upperarm)	1.2 (0.7)	<.001	
ID (forearm)	2.5 (2.1)		
ID (forearm)	2.0 (1.6)	.250	
IM (upperarm)	1.7 (1.4)		
Undressing for injection perceived as negative			
ID (upperarm)	4.1 (2.7)	.700	
ID (forearm)	3.8 (3.1)		
ID (forearm)	2.9 (2.4)	.010	
IM (upperarm)	4.4 (2.6)		

\+ Paired Samples T-Test between ID injection upper arm and ID injection forearm (ID group; n:51)
++ Paired Samples T-Test between ID injection forearm and IM injection upper arm (IM group; n:51)
o refers to outliers with an interquartile range between 1.5 to 3
* refers to extreme outliers with an interquartile range >3
All injections contained sterile, pyrogen free 0.9% NaCl solution (Mini-Plasco, B. Braun). The solution was injected at room temperature.
For IM injections 0.5cc was injected, while 0.1cc was injected via the ID route using VAX-ID.
The presence of local reactions was scored by a Visual Analogue Scale (VAS): 1 = no presence and 10 = strong presence.

Local reactions reported on day 1 after injection (n:96)

	ID group (n:49)			IM group (n:49)		
	ID injection upper arm Mean (SD)	ID injection forearm Mean (SD)	p*	ID injection forearm Mean (SD)	ID injection upper arm Mean (SD)	p+
Pain§	1.12 (0.44)	1.10 (0.37)	.785	1.04 (0.20)	1.64 (1.01)	<.001
Redness§	1.10 (0.37)	1.27 (0.61)	.031	1.11 (0.32)	1.26 (0.64)	.109
Redness in mm	0.14 (0.50)	0.20 (0.58)	.261	0.33 (1.37)	0.93 (3.06)	.211
Swelling§	1.00 (0.00)	1.00 (0.00)	-	1.02 (0.15)	1.06 (0.25)	.569
Swelling in mm	0	0	-	0	0.19 (0.83)	.197
Ecchymosis§	1.00 (0.00)	1.00 (0.00)	-	1.04 (0.21)	1.13 (0.54)	.710
Ecchymosis in mm	0	0	-	0	0.30 (1.16)	.162
Hardening/induration§	1.02 (0.14)	1.00 (0.00)	.322	1.07 (0.33)	1.19 (0.54)	.323
Hardening in mm	0.08 (0.57)	0	.322	0.02 (0.15)	0.19 (0.54)	.083

* Paired samples T-test between ID injection upper arm and ID injection forearm.
\+ Paired samples T-Test between ID injection forearm and IM injection upper arm.
§ The presence of local reaction was scored by a Visual Analogue Scale (VAS):
1 = no presence | 10 = strong presence

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