

YOUR DEDICATED PARTNER IN DRUG SAFETY

Vascular Access Port (VAP) Usage in Minipigs



Access to the venous system in the minipig to facilitate routine or serial blood sampling and repeated intravenous bolus injections or continuous infusion has historically caused difficulties due to the nature and physiology of the test species. A study was performed at ITR to allow the development of techniques for the surgical implantation of a single vascular access port (VAP) to optimize procedures for blood sampling or dose administration. An evaluation of alternative routes for intravenous catheterization using an externalized catheter to allow for repeated or routine injection/infusion of solutions in the Göttingen Minipig was also

performed in a single vessel per animal. Both methods are considered to be less stressful to the animals and also requires fewer technicians to perform. The blood vessels selected for catheterization were the external jugular and the cephalic vein near to the junction with the Jugular vein.

A total of 4 (2 males and 2 females) mini pigs were randomly assigned to study as described in the table below:

Animal	Group Designation	Location of Catheter implantation	VAP (Lock Solution)	Dose Rate (ml/kg/hr)			
				Week 1	Week 2	Week 3	Week 4
1 (male)	Catheter	Cephalic	NA	1	2	3	4
2 (female)	VAP	Jugular	Sodium# Heparin/ Saline	-	-	-	-
3 (male)	VAP	Cephalic	Saline	-	-	-	-
4 (female)	Catheter	Jugular	NA	1	2	3	4

= The concentration of the sodium heparin solution was 100 IU/mL

Following surgery, the VAP's were flushed with saline solution and locked with the appropriate solution as specified above. Mini pigs with externalized catheters received 0.9% Sodium Chloride for Injection, USP at a rate of 5 mL/h through a catheter attached to a swivel device, via a jacket and tether system, until the start of the treatment regiment outlined above.

Animals 1 and 4 were administered the control article (0.9% sodium chloride for injection USP) for 28 consecutive days by intravenous infusion via the surgically implanted catheter over a period of 24 hours/day during Weeks 1 and 2 and over a period of 6 hours/day during Weeks 3 and 4. No difficulties were encountered during the in-life phase of the study.



Animals 2 and 3 were administered the control article (0.9% sodium chloride for injection USP) once daily by intravenous injection via the VAP at a dose volume of 1 mL/kg for 28 consecutive days. A series of 4 blood samples (approximately 1 mL each) were collected via the vascular access port from each Minipig on each of Days 1 and 28 of the treatment period at 1, 2, 4 and 24 hours after treatment via the VAP.

NOTE: although the VAP was used for dosing and blood sample collections in this study this will not be the case for a client sponsored study as intravenous dosing would be performed using another VAP implanted in the contralateral vein or utilizing an alternative vessel as appropriate.

VAP related incidents included one dosing occasion, out of a total fifty six (56), where the Vascular Access Port was initially occluded, however, after manipulation the Control article was administered (injected) with ease. On a separate occasion a repair surgery was performed due to a mechanical blockage in the catheter. The repair was successful using the same blood vessel. There was no difficulty (occlusion of the VAP), encountered during the lock/blood withdrawal procedures.



In conclusion the results of the study suggest that vascular access ports (VAPs) are safe, reliable and less stressful for repeated or routine injection of solutions and for routine or serial blood sampling. The study also confirmed the possibility of using the jugular and cephalic vein as alternate routes for intravenous catheterization (in comparison with femoral vein) for repeated or routine injection/infusion of solutions in the

Göttingen Minipig. It is also considered that a jugular catheterization could be complimented by a VAP implantation in the contralateral cephalic vein in the same animal to optimize blood collection or treatment strategies.



*ITR Canada wishes you a happy Holiday Season
and a prosperous New Year*

