PANMANAGEMENT Subcutaneous Delivery Route

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PALLIATIVE CARE

A major goal of palliative care is to provide comfort. Care at the end of life should be responsive to the personal needs and preferences of the patient. The subcutaneous (SC) route has become a favored route of administration in palliative care due to its flexibility, safety and practicality¹. The SC Route is particularly useful for patients with dysphagia, nausea and vomiting, or bowel obstruction^{2,3}.

SUBCUTANEOUS DELIVERY ROUTE

Each patient will have different symptoms, depending on their condition and the kind of treatment they may be having, and each patient must be evaluated on an individual basis. The most common sites for the infusion set to be inserted are back of upper arm, abdomen and thigh. It is important to consider comfort and safety and whether the patient is still able to get out of bed or is in a confused state, and the rotation of insertion sites.

DRUG/DEVICE STABILITY TESTS

It is recommended that some areas are avoided, including the following:

SC VERSUS IV

When people are unable to take medication orally those medications can be administered either intravenously (IV), intramuscular (IM) or by infusion into the subcutaneous (SC) tissues.

Subcutaneous delivery has many advantages over IV infusions, including less discomfort to the patient, ease of administration and cost effectiveness^{4,5,6}.

Bloodstream infections are a critical issue for health care facilities around the world. 60% of all hospital-acquired bloodstream infections originate from some form of vascular access⁷. Infection complications are less frequent and less severe with subcutaneous infusion than with the IV route¹.

According to Medical Device MDD 93/42/EEC healthcare professionals must be able to rely on medical device manufacturers to perform adequate test to establish safe and effective use.

To ensure that ConvaTec Infusion sets during normal use does not have any negative influence on the stability of medication, drug/device stability tests have been carried out by external institutes like IKFE and Teknologisk Institut.

THE TEST COVERS THE FOLLOWING DRUGS:

Pain Management

- Hydromorphone hydrochloride
 - Morphine Sulfate

Morphine Chloride

Rehydration

• Saline



- Areas of inflammation.
- Tumour sites.
- Close to broken skin.
- Bony prominences.

DRUG/DEVICE TEST METHOD

In the United States Pharmacopoeia (USP), for HPLC analysis of morphine sulfate and hydromorphone samples, opioid quantification is described. Utilizing HPLC methodology (according to the USP 33 – NF 28), it is possible to determine opioid quantity after infusion device passage and potential opioid degradation associated with infusion device passage.

Pumps with morphine sulfate and hydromorphone filled syringes will be connected to the infusion set and will be incubated at 37°C (simulating body temperature) for the 144 hours of study conduct. The opioid samples will be collected after infusion device passage at time points Oh, 24h, 48h, 72h, 96h, 12Oh, and 144h and is subject to HPLC analysis. Furthermore, Device Compatibility tests were conducted to detect any physical changes in infusion set, after being exposed to the drugs and in a test environment of 37°C⁹.



Advantages of the subcutaneous delivery route for Pain Management

- Results in morphine levels equivalent to IV route
- Relative potency is equivalent to IV route
- Suitable for home management
- Less discomfort to the patient
- Availability of Subcutaneous access sites is larger
- Less visible and less restrictive than traditional IV treatment
- Ease of administration
- Cost effectiveness

NERIA GUARD / CONVATEC

ConvaTec offers a range of infusion sets for subcutaneous infusion which have all been drug/device stability tested for safe use with medication indicated for targeted disease areas. The latest development is the neria guard[™] infusion set which is a fully automated device for placement of the cannula in situ without direct contact with the needle.

Our products are also used in treatment of Parkinson's Disease, Primary Immune Deficiency, Rehydration, and Thalassaemia with equivalent drug/device testing as documentation.

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Some manufacturers have developed subcutaneous devices that incorporate both hypoallergenic dressings and integral sharps protection. One such recent development is the neria[™] guard. Neria[™] guard is intuitive to use, resulting in a quick and reliable procedure for placing a subcutaneous infusion device at the correct angle of 90 degrees. The insertion needle is also automatically withdrawn into the 'housing' unit as soon as the cannula is inserted, thereby protecting staff from risk of sharps.⁸"



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Infusion Care

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1. Kestenbaum MG et al. Alternative routes to oral opioid administration in palliative care: a review and clinical summary. Pain Medicine 2014;15:1129-1153. 2. Mercadante S et al. Alternatives to oral opioids for

