Administration of Seizure Rescue Medications via Autoinjector

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Ease of use
- Fixed dose delivery
- Safety features
  - Single use, disposable
  - Hidden needle
  - "Automated" needle insertion, retraction
  - Push button
  - Nose-activated
- Established use in other conditions
  - Anaphylaxis
  - Multiple sclerosis
  - Rheumatoid arthritis
  - Military use

Autoinjector Features

Autoinjectors
- Department of Defense Autoinjector
- Meridian Medical Technologies™

IM Midazolam Administration via Autoinjector
- RAMPART (Rapid Anticonvulsant Medication Prior to Arrival Trial)
- Compared with intravenous lorazepam
- Adults and Children with convulsions persisting for more than 5 minutes
- Administered by paramedics into thigh
- Autoinjectors supplied by Department of Defense

RAMPART Results
- Seizure Termination
  - 74 % in IM midazolam group
  - 64% in IV lorazepam group
- Intubation Required
  - 14.1% with IM midazolam
  - 14.4% with IV lorazepam
- Seizure Recurrence
  - 11.4 % with IM midazolam
  - 10.6% with IV lorazepam

RAMPART Results
- Time to initiating active treatment
  - 1.2 minutes with IM midazolam
  - 4.8 minutes with IV lorazepam
- Time from administration of treatment to stopping convulsions
  - 3.3 minutes with IM midazolam
  - 1.6 minutes with IV lorazepam
25% of patients did not stop seizing with the “best” treatment
50% were hospitalized
Might patient-specific doses/different injection devices improve response?
How might previous administration of rectal diazepam affect the outcome?
How do these results compare with alternate methods of midazolam administration?

- Comparison with diazepam rectal gel
- Studies conducted in volunteers without seizures
- Subjects rated pain/discomfort, mode of administration preference
- Nurse rated difficulty of administration
- Safety evaluated
- Diazepam blood levels measured

Discomfort/pain reported more often with IM administration
Decreased with time
71% of subjects preferred IM administration
Nurse rated IM treatment as least difficult to administer
No effect on breathing
Drowsiness, sedation, headache, dizziness in both groups
Slightly higher, more reliable blood levels with IM administration

Evaluating the safety and effectiveness of Vanquix Autoinjector
2 years of age and older
Caregiver administration
Evaluation of time to next seizure or rescue medication
% of subjects requiring additional rescue therapy
% of subjects requiring Emergency Room visits
Caregiver evaluation of treatment outcome
Estimated study completion: July 2013

Autoinjector technology for seizure rescue medications:
May offer alternatives for administration of seizure rescue medications
IM medication delivery can be accomplished faster than IV administration by paramedics with comparable effectiveness
Preferred by subjects over rectal diazepam administration
Ease of use, convenience, social acceptance
May offer a reliable option for caregivers of patients with acute seizure presentations