

Internal Contamination due to Actinide Injection Injuries

double, double
toil, trouble and confusion:
-Obfuscations from recent cases-

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INDs & NDAs

- Definitions:
 - IND: Investigational New Drug application; the FDA classification of an investigational drug
 - NDA: New Drug Application: FDA classification of a drug newly released to the open market, for use by physicians and sold in pharmacies

Diethylenetriaminepentaacetic Acid (DTPA) INDs & NDAs

- Ca- and Zn-DTPA
 - an effective and safe drug for chelation/removal of actinide internal contamination
 - Available as both an IND and a NDA product

DTPA

INDs & NDAs

	IND	NDA
Investigational	Yes	no
Available in Pharmacies	No	yes
FDA approved for chelation of Pu, Am and Cm	yes	yes
FDA approved for other actinides, lanthanides, etc	yes	no
Need informed consent form	yes	no

Difference: INDs & NDAs

	IND	NDA
Admin: IV push, IV infusion	yes	yes
Admin: inhalation	yes	yes
Admin: IM	Yes	No
Experience with vender	9 yrs	2 yrs
SAE, AE	No	No

Difference: INDs & NDAs

	IND	NDA
Dose	1 gm/day	1 gm/day
Irrigation	No particular benefit & \$\$	No particular benefit & \$\$
Cost	Expensive	~8 times cost of IND product
Give Ca-DTPA to pregnant female	No	No

DTPA

- DOE DTPA IND Safety and Efficacy Study:

Uses IND product!

- Therefore co-investigators must:
 - Obtain written informed consent
 - Plus written approval for REAC/TS registry

IND product DTPA

- FDA approved IND protocol requires:
 - Injection injury
 - Spot urine before treatment
 - 24 hour urine (or equivalent) after treatment or other bioassay technique
 - WB scan if available

IND product DTPA

- FDA approved IND protocol requires:
 - Inhalation or injection:
 - Spot urine before treatment
 - 24 hour urine after treatment x days
 - 24 hour faecal collection x days
 - WB Scan if indicated

IND product DTPA

- FDA approved protocol requires:
 - H & P
 - Various lab tests: CBC, urine, electrolytes
 - Completion of reporting form for SAE, AE
 - Exceptions?
 - Spot urine and 24 hr urine for quantitative radionuclide identification and analysis
 - Faecal analysis if inhalation or ingestion
 - Scan if indicated and available

Administration of DTPA

- When to administer:
 - Administer Ca-DTPA within 6 hours of contamination event, unless pregnant female
 - Yes, check for pregnancy
 - Sooner the better
 - Before excision:? Some controversy but yes
 - Contaminated person's age less than 45 yrs old

RC965
.R2589
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Handling of Radiation Accidents

PROCEEDINGS
OF A
SYMPOSIUM,
VIENNA,
19-23 MAY 1969

ORGANIZED BY IAEA
IN COLLABORATION WITH WHO



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Administration of DTPA

- Decision to administer DTPA:

Remember:

- HP or internal dosimetrist may not be able to give good dose estimate with the first 6 hours,
- there may be confounding reports of dose level and chemical characteristics of radionuclide:
- Final decisions is physicians

Administration of DTPA

- Decision to administer
 - Significant internal contamination identified
 - Consult with senior HP or internal dosimetrist
 - Suspicion of significant internal contamination
 - Consult with senior HP or internal dosimetrist
 - Either of the above with patient less than 45 yrs old
 - **WHEN IN DOUBT: TREAT!**

Administration of DTPA

- Again-WHEN IN DOUBT:

TREAT!

- DTPA if given within the first 6 hours can remove 80-90 % of the radionuclide in the circulation & is safe

Administration of DTPA

- Both Ca- & Zn- DTPA have proven safe, with few side effects and no AE or SAE if given as directed on the label:

Administration of DTPA

- Give 1 gm Ca- or Zn-DTPA/day maximum
- Give Ca-DTPA for first day only
- Following days give Zn-DTPA, as indicated
- Base treatment on biodosimetry results

Administration of DTPA

- Do not give Ca-DTPA to pregnant women (and check for pregnancy)
- Does your clinic have a rapid pregnancy test card? If not, you should!

QUESTIONS?

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