

ESETT USE NEXT BOX

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Use Next Box – Study Drug Strata

Use Next Box color will correlate to study drug strata

<18 years	children = purple
18-65 years	young adults = yellow
>65 years	older adults = gray

Contents

- Protocol Assist Device – iPod
- Study Drug Vial
- Broselow-like tape
- Dosing Chart
- Inclusion/Exclusion Criteria
- Instruction Card
- iPod charger



Study Drug Vial



Study Drug Vial

4504

ESETT Study Drug



fosphenytoin 16.66 mg PE/ML, valproate 33.33 mg/ml, or levetiracetam 50mg/ml.

PE= phenytoin equivalent.

I.V. Solution in 0.9% sodium chloride injection.

This vial contains 100 mL.

IND Number:119756

Caution: New Drug - Limited by Federal Law to Investigational Use

Manufactured by University of California, Davis

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I.V. solution in 0.9% sodium chloride injection



Length Based Weight Estimation

Colors match
Broselow

Use only for
Children



◀ MEASURE FROM THIS END



ESETT

LENGTH BASED WEIGHT ESTIMATION TOOL
FOR INVESTIGATIONAL USE ONLY

DO NOT ENROLL

RED
9 mL in 10 min
0.9 mL/min

PURPLE
12 mL in 10 min
1.2 mL/min

YELLOW
15 mL in 10 min
1.5 mL/min

WHITE
18 mL in 10 min
1.8 mL/min

Length Based Weight Estimation



MEASURE FROM THIS END

Pocket Card



Investigator HOTLINE:
1-855-ESETT-PI (373-8874)

-Inclusion Criteria-

- Seizing for >5 minutes
- Continued/recurring now despite adequate benzo
- Last dose of benzos given >5 minutes ago
- Last dose of benzos given <30 minutes ago
- Age \geq 2 years (and \geq 7.5kg)

-Exclusion Criteria-

- **Known** pregnancy, severe metabolic/liver/renal disease
- **Known** allergy or contraindication to:
 - phenytoin (Dilantin), fosphenytoin (Cerebyx),
 - levetiracetam (Keppra), or valproic acid (Depakote)
- **For this episode** of status epilepticus already...
 - given intravenous 2nd line anticonvulsant or
 - non-benzo sedatives with anticonvulsant properties (propofol, etomidate, ketamine, etc) or
 - endotracheally intubated
- Status epilepticus thought to be caused by:
 - hypoglycemia < 50 mg/dL
 - hyperglycemia > 400 mg/dL
 - acute traumatic brain injury
 - cardiac arrest/post anoxia
- Prisoner
- Opt-out identification declining ESETT



DOSE ADMINISTRATION CHART

Estimated Weight (Kg)	Infusion Volume (total mL)	Rate (mL/min over 10 min)	length based color (peds only)
0 - 7.4	Do Not Enroll		Grey
			Pink
7.5 - 9.9	9	0.9	Red
10 - 12.4	12	1.2	Purple
12.5 - 14.9	15	1.5	Yellow
15 - 19.9	18	1.8	White
20 - 24.9	24	2.4	Blue
25 - 29.9	30	3.0	Orange
30 - 34.9	36	3.6	Green
35 - 39.9	42	4.2	
40 - 49.9	48	4.8	
50 - 59.9	60	6.0	
60 - 69.9	72	7.2	
70 - 74.9	84	8.4	
\geq 75	90	9.0	

Established
Status
Epilepticus
Treatment
Trial

Patient still seizing? Go to ESETT

1 IDENTIFY PATIENTS

Look for patients who received enough benzos and are still seizing, who now need a second line anticonvulsant (fos-phenytoin, valproic acid or levetiracetam).

Remember...adequate benzos given + still seizing = GO to ESETT!

keppra, depakote
dilantin, cobyk



2 GET THE ESETT BOX

Correct color box for age.
Review Exclusions on the Pocket Card
Open Box, Turn On the iPod.



3 GO SPIKE VIAL & HANG FOR IV PUMP OR DRAW UP FOR SYRINGE PUMP

☆ -Estimate Weight,
-Prime the Line
-Set the Rate and Volume
(see dosing chart)

then you should

-GO! Start Pump,
-Touch GO on iPod.
-Hang Fluid to Chase
(if needed).

Very Low HR or BP?
Give Fluid,
Reduce Rate



4 STOP INFUSION AT 10 MINUTES

(iPod will remind you. Take down infusion)

Allow Drugs to Work for 10 Minutes *Don't give other anticonvulsants until needed*

Say What You See When You See It... example "Convulsions stopped"

Still Convulsing after 10 min → 3rd Line (or preferred rescue)

Not Convulsing? Continue to Watch

Usually should NOT intubate.
This is what we want 2nd Line to do

5 STUDY TEAM ARRIVES OR CONFIRM THEY ARE ON THE WAY

Collect the box (or put in a safe place).

Tell study team if rescue meds were given and if family is present.

YAY...YOU DID IT!

Instruction Card

iPod Charger and Tether



Storage

- Secured area
- Temperature controlled: 2-8 degrees C
- Easily accessible by clinical team
- Ongoing reminders to clinical team
- Back-up study drug vial stored in pharmacy



Subject Enrollment

- Treating team will use the matching Use Next Box based on the subject's estimated weight
- Length based weight estimation tool



Restocking

- Enter randomization CRF in WebDCU™ within 8 hours
- Restock with back up vial*
- Charge iPod
- Reload length based weight estimation tool
- Reload iPod charger

*Nothing is entered into WebDCU™ for the back-up vial

Study Drug Replacement

- Enter randomization information into WebDCU™
- Next treatment assignment will be shipped
- Restock Use Next Box with back-up study drug vial
- New vial arrives, exchange with back-up vial
- Return back-up vial to pharmacy



Supplies and Contacts

- Need more boxes? Supplies?
ESETT-Supplies@umich.edu
- ESETT Site Managers

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