Accrual and Attrition

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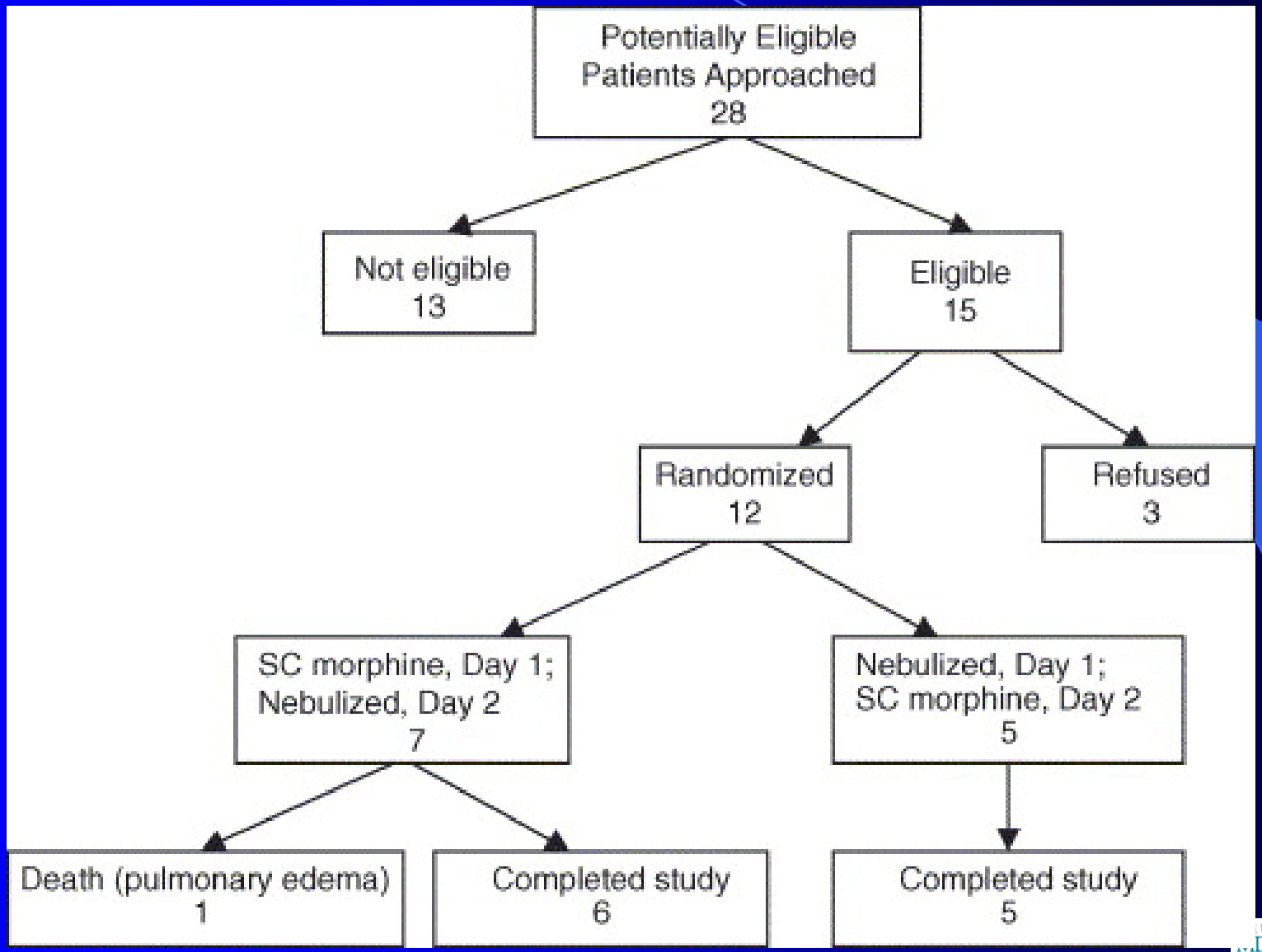
Accrual

- Not possible to include enough patients in a study

Nebulized vs. Subcutaneous Morphine



Bruera et al, JPSM 2005

Nebulized morphine Vs placebo- 12/48 pts admitted

- Inclusion criteria: continuos dyspnea (distress, delirium)

Solution:

Exercise patients (6 min walk)

Earlier patients (lung cancer clinic)

- **Double blind parallel RCT EPO SC weekly Vs placebo for fatigue in advanced cancer pts with mild/moderate anemia**

EPO Vs placebo for fatigue 1/40 pts included

- Competing with easier studies (less assessments)
- Pts not readily available (no “fatigue” primary service)

Solutions:

Budget 60% of time for patient finding

Per patient payment cannot be only for study completion

Testosterone replacement pilot study- 2/ 50 pts admitted

- Inclusion criteria: no chemo/ hormones
- Blood level and wait 3-5 days
- Repeated visits

Solutions:

Less stringent criteria, draw blood in 1st visit, telephone follow up

Bisphosphonate for symptoms of osteolysis- 2/ 78 pts admitted

- Drug Vs placebo in 5 day IV injection
- 50% chance of placebo- research RNs not convinced….
- Not enough for pt and family

Solutions

Decrease injections, cross- over after primary outcome, pay for transportation and parking

Attrition

- Patients agree to participate and are admitted to the study but do not complete

Cyproheptadine 32 mg/day Vs placebo for appetite- stopped at pt 13

- All pts receiving CH had sedation- loss of blinding

Solutions:

Open pilot study with measurement of primary enpoint and side effects at different dose

Active placebo?

Donepezil 5 mg/day open for opioid sedation- 9/15 pts dropped – side effects

- Inexperienced research RN- Patient/ family hypervigilant, symptoms ascribed to D

Solution

Train research personnel (drug pharmacology, protocol, role playing!!)

130 pts- 8 % drop-out rate

Methadone Q-T prolongation- 5/35 pts completed

- 4 week follow up requirement
- Hospital visit for EKG
- Nothing for pt/ family

Solution

Assess at week one, pay transportation- parking,

Accrual issue: include pts with long QT

Main reasons for low accrual/ high attrition

- **Most studies are dead before activation !**
- Criteria for inclusion
- Overestimation of eligible patient #
- Poor training of research assistants/ fellows
- Complex logistics (multiple injections, labwork, visits)

Tips for best accrual/ attrition ratio

1. **Include clinicians in the design**
2. **Simplify inclusion criteria (town Vs gown)**
3. **Do not measure all outcomes (except pilots)**
4. **Budget 60% pt finding**
5. **Collaborators!! (oncologist, cardiologist)**
6. **Telephone for adherence/ outcomes**
7. **What is there for pt/ family (open phase, waiting list, transportation, RN phone call)**
8. **Monitor weekly!!**