

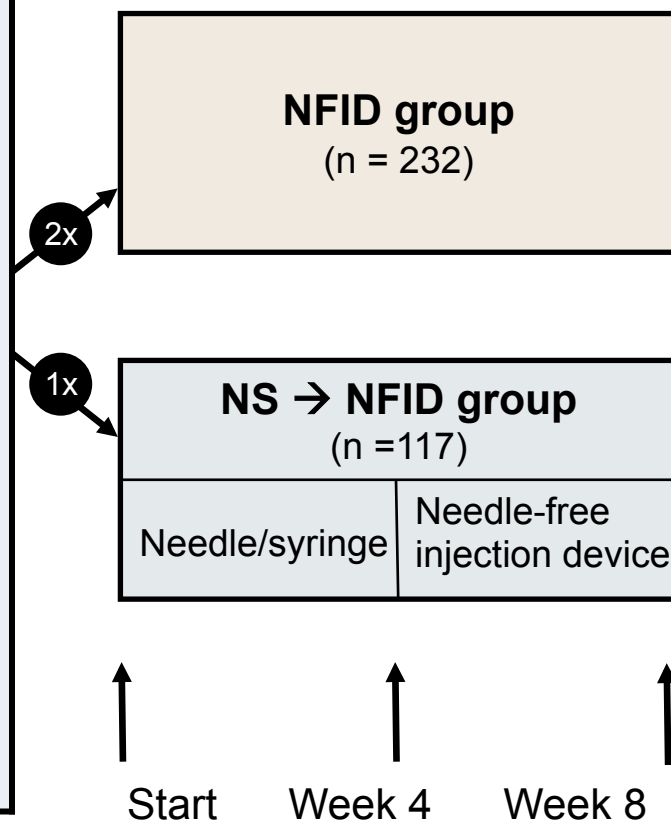
Enfuvirtide Needle-Free Injection Device (NFID) versus Needle
BOSS Study

Enfuvirtide Needle-Free Injection Device vs. Needle/Syringe

BOSS: Study Design

Study Design: BOSS

- **Background:** Open-label, single-arm, crossover phase 4 study comparing the injection site reaction signs and symptoms of enfuvirtide when administered with a standard needle/syringe versus a needle-free injection device (NFID) in enfuvirtide-experienced patients
- **Inclusion Criteria (n = 349)**
 - Age ≥ 16 years of age
 - Difficulty tolerating long-term (>4 weeks) enfuvirtide with standard needle/syringe
 - Willing and able to self-inject enfuvirtide (or had a caregiver)
- **Treatment Arms**
 - ENF 90 mg SC BID via NFID
 - ENF 90 mg SC BID via NS x 4 weeks, then switch to NFID

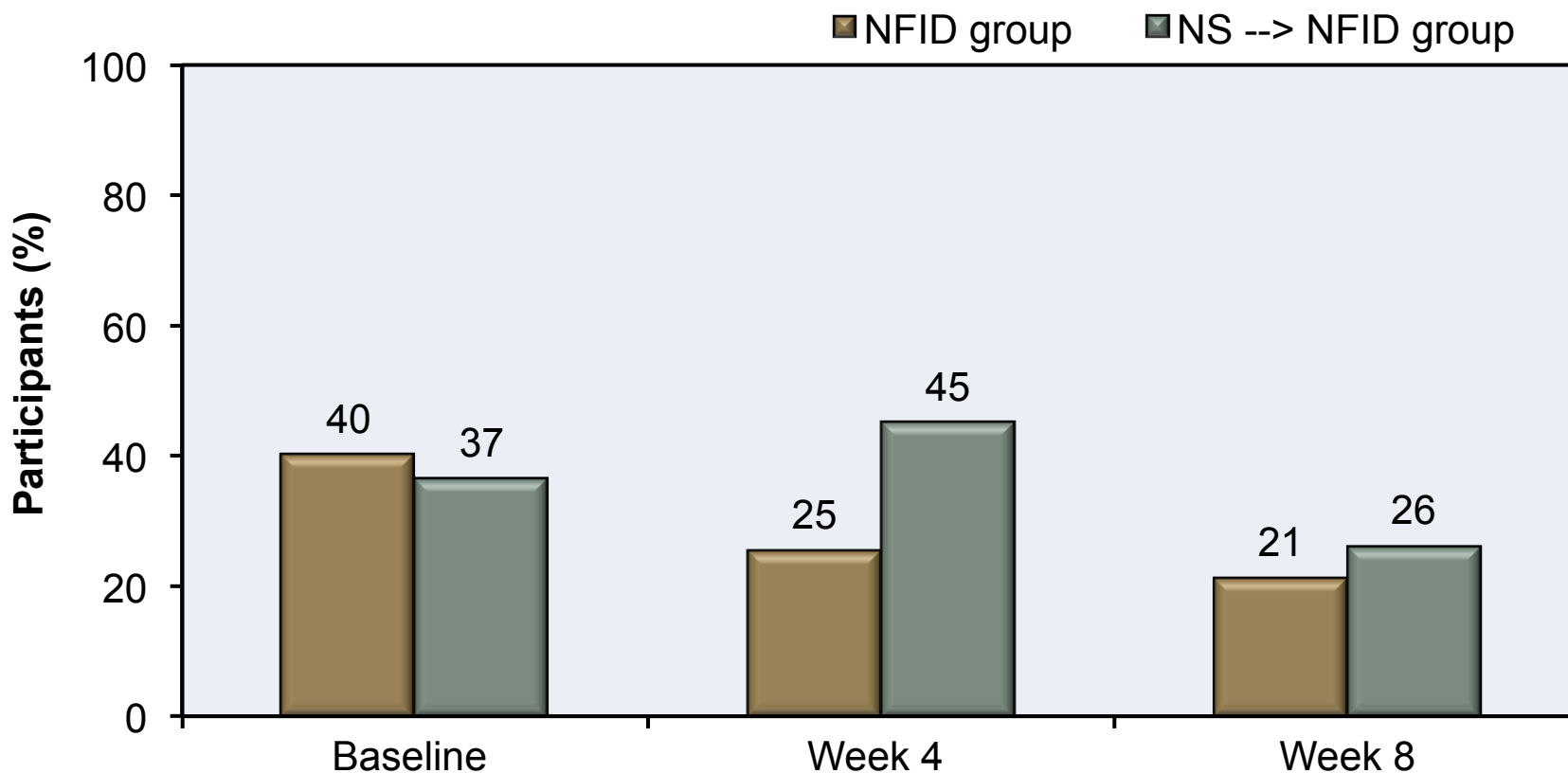


BOSS = Biojector 2000 Open-label Safety Study

Source: Lalezari JP, et al. *AIDS Res Hum Retroviruses*. 2008;24:805-13.

Enfuvirtide Needle-Free Injection Device vs. Needle/Syringe BOSS: Result

Participants Meeting Composite Primary Endpoint*

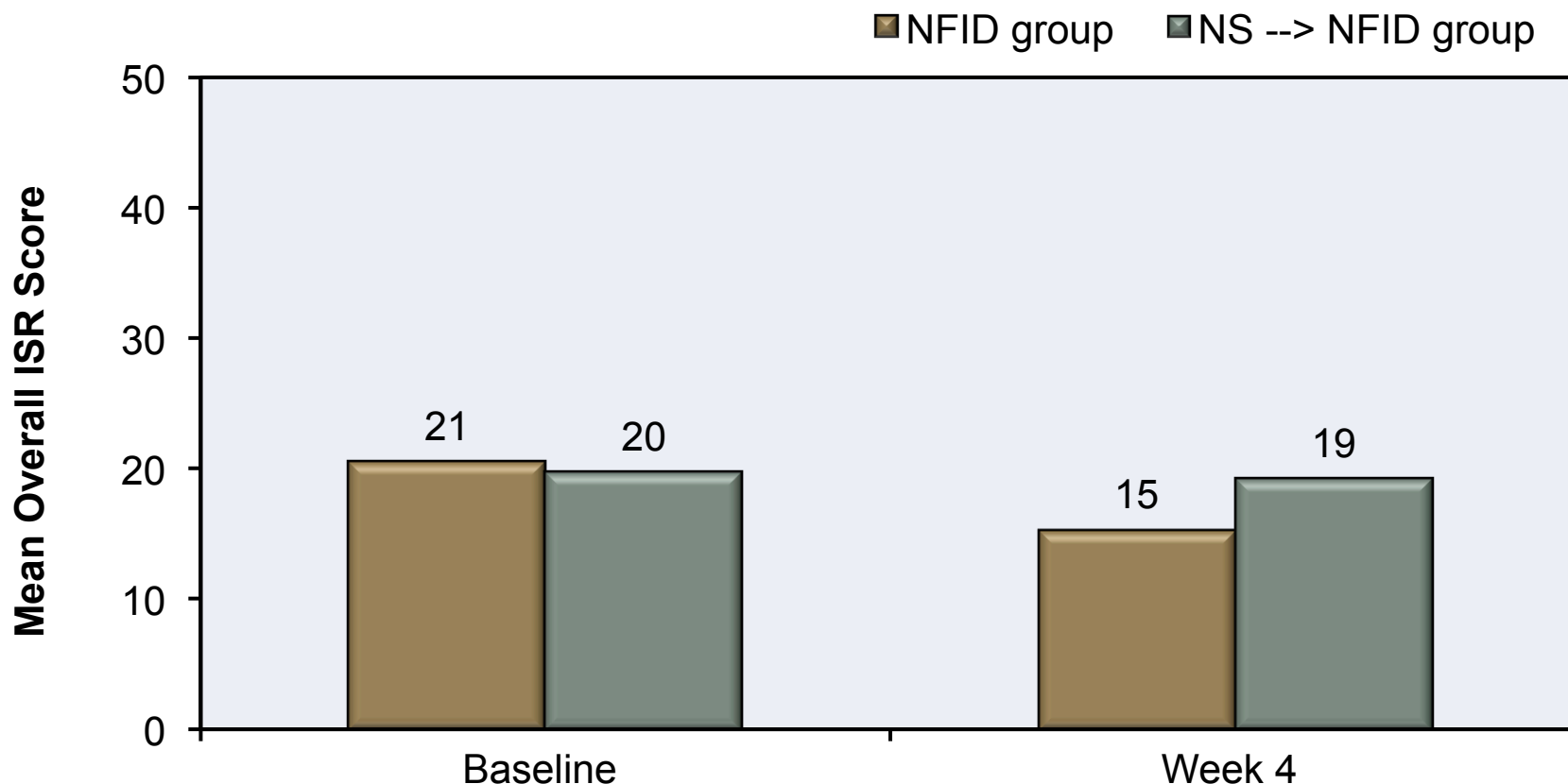


*Composite primary endpoint = grade 1–3 ongoing pain and either grade 3–4 induration (>25 mm) or grade 2–4 nodules/cysts (≥ 20 mm)

Source: Lalezari JP, et al. *AIDS Res Hum Retroviruses*. 2008;24:805-13.

Enfuvirtide Needle-Free Injection Device vs. Needle/Syringe BOSS: Result

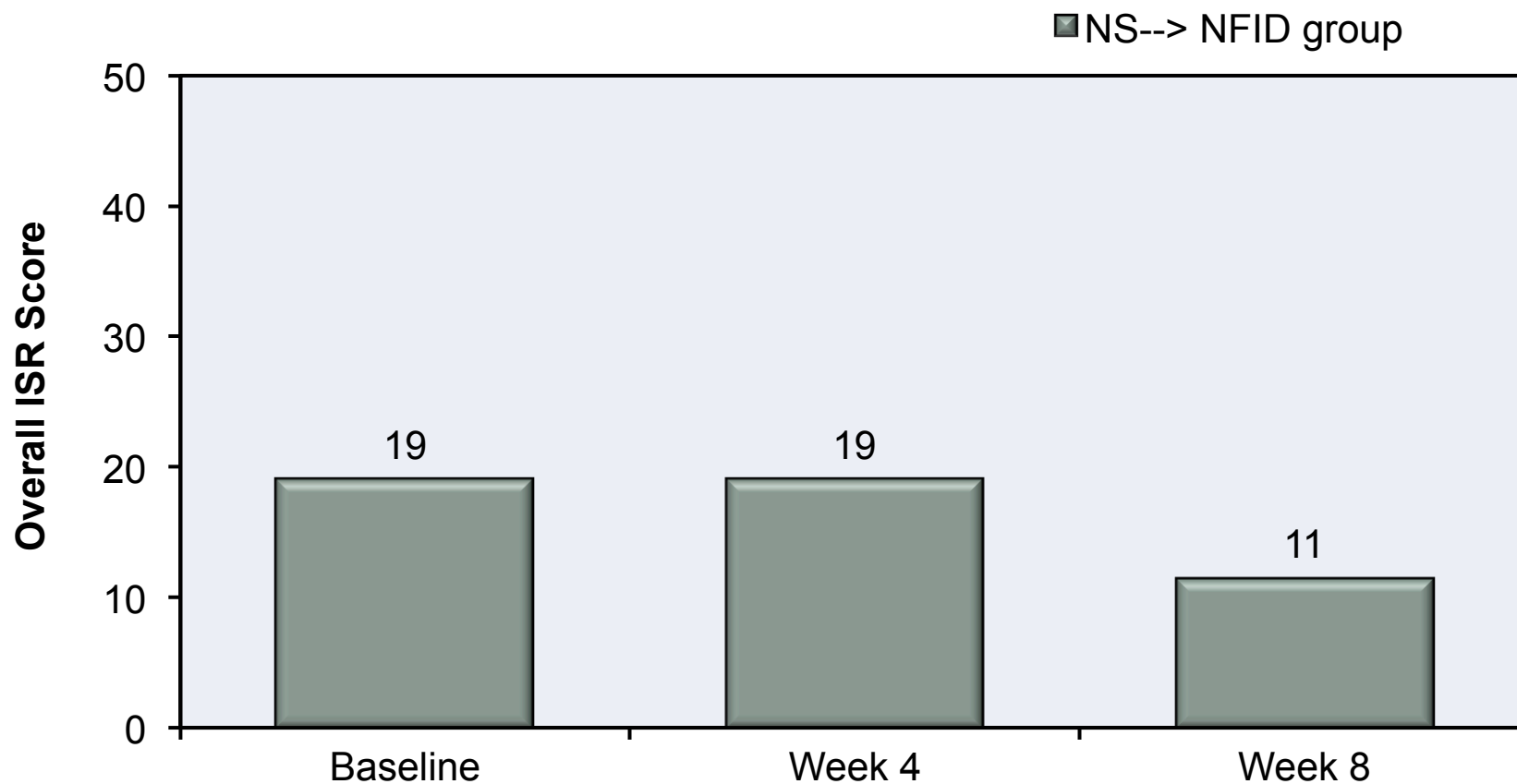
Injection Site Reaction (ISR) Score: Between-participant comparison



Enfuvirtide Needle-Free Injection Device vs. Needle/Syringe

BOSS: Result

Injection Site Reaction (ISR) Score: Within-participant comparison



Enfuvirtide Needle-Free Injection Device vs. Needle/Syringe

BOSS: Conclusions

Conclusions: “NFID is an alternative injection method that may reduce the incidence and severity of treatment-limiting ISRs associated with ENF administration.”

Acknowledgment

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The content in this slide set does not represent the official views of the U.S. Department of Health and Human Services, Health Resources & Services Administration.

