

20. Klinický den ČSNM

KC SOLID, spol. s r.o.

23.dubna 2005



 IMMUNOMEDICS®, INC.

Partner für die Nuklearmedizin



LeukoScan v dubnu 2005...

- V ČR zavedený přípravek s dobrými zkušenostmi, využití zejména v oblasti osteomyelitid
- Distribuce ze skladových zásob KC SOLID, spol. s r.o. (exp. nyní 07/2006)
- Evropská registrace, nedávné schválení v Kanadě



Klinické využití

- Souhrn:
- Osteomyelitidy...
- Akutní atypické apendicitidy
- Horečky neznámého původu, endokarditidy...
- + *dodatek: břišní záněty zatím nepřesvědčivé*
Nucl Med Commun. 2005 Mar; 26(3):245-54
Eur J Nucl Med Mol Imaging 2002 Feb;29(2):251-4
Pediatr Radiol. 2001 Nov; 31(11):796-800



LeukoScan aplikace kojícím ženám

- „Measurement of radioactivity in breast milk following 99mTc-LeukoScan injection“
Nucl Med Commun. 2004 Sep;25(9):963-6
- Dávka pro kojence nižší než 1 mSv splněna po 10-hodinovém přerušení kojení (aplikováno 750 MBq)

Immunoscintigraphy of Infection with Fab' Fragments

Miguel de la Guardia, BS, RT(N)

Senior Manager,

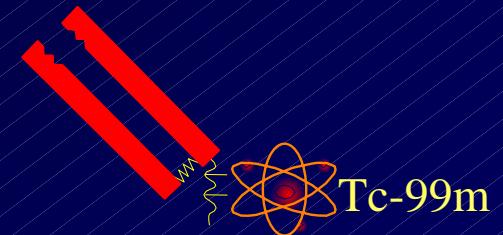
Sales & Marketing Services

Immunomedics, Inc.

Fab' Fragments

- **One arm for binding to target:**
 - Penetrate tissues rapidly and thoroughly.
 - Faster clearance from blood pool than IgG.
 - Lower uptake in the liver than IgG.
- **Even though anaphylactic and other hypersensitivity reactions are possible following administration of mouse protein to patients.**
 - Fc group - the most immunogenic part of the molecule.
 - Eliminates much of the immunogenicity observed with mouse derived antibody products.

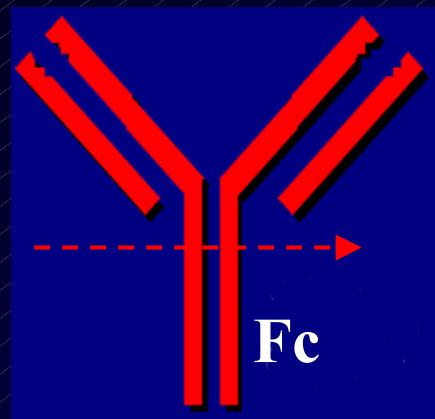
CEA-Scan &
LeukoScan



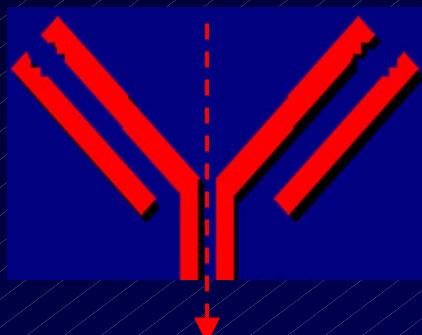
Tc-99m

What is LeukoScan® (Sulesomab)?

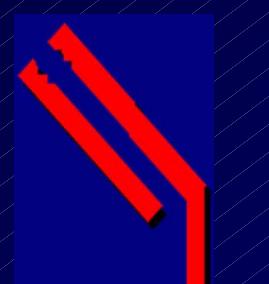
- Murine monoclonal antibody fragment specific for surface glycoprotein designated as Nonspecific Cross-reactive Antigen (NCA-90) on neutrophils



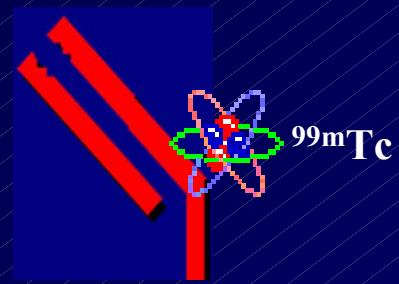
Intact
Antibody



F(ab')₂
Fragment



Fab'
Fragment
Sulesomab

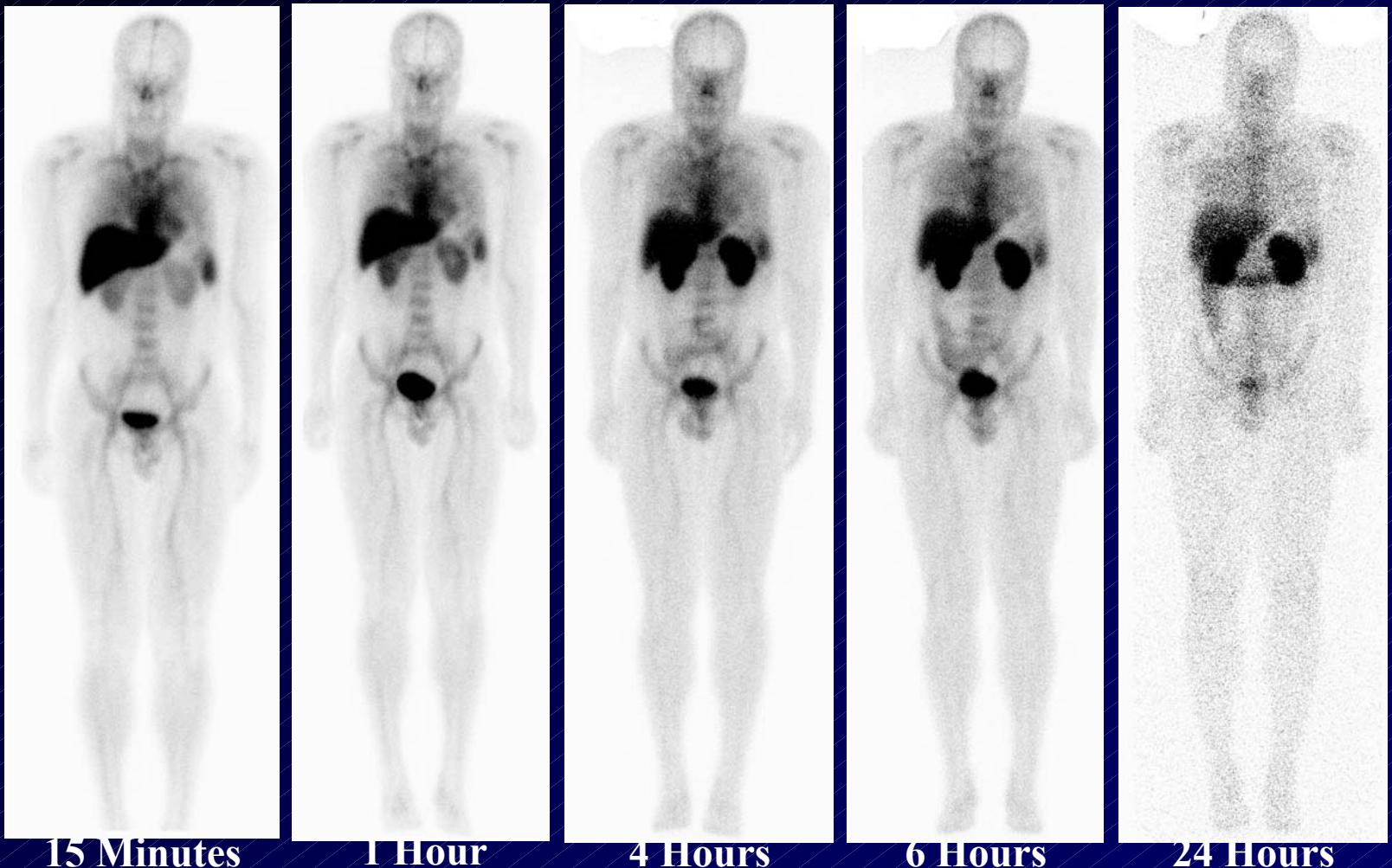


Labeled
Sulesomab

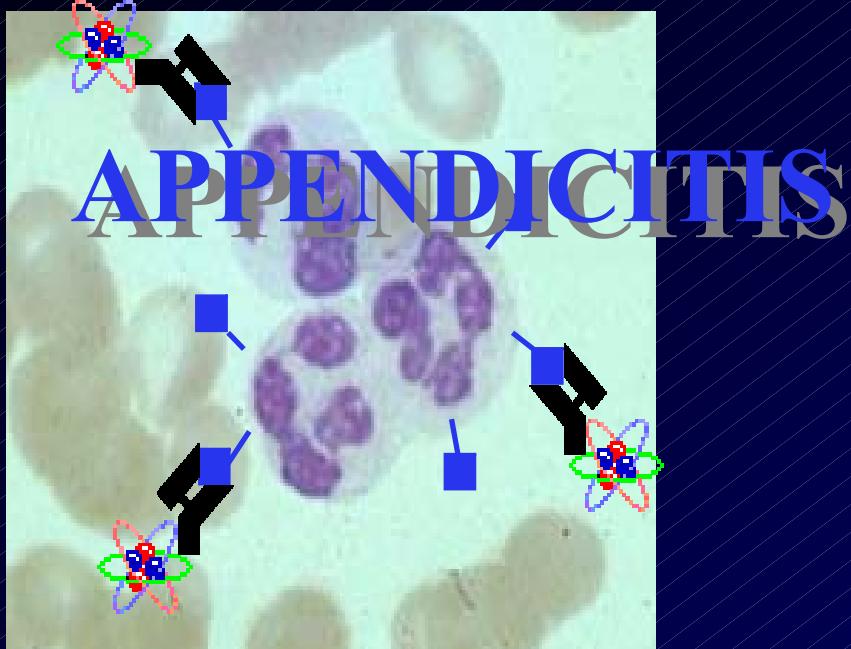
LeukoScan Product Profile

- Murine antibody fragment preferentially targeting activated neutrophils (NCA-90).
- No ex-vivo blood handling- improved safety for hospital personnel and patients.
- Recommended Imaging:
 - ◆ < 4 hours post-injection for appendicitis or abdominal imaging.
 - ◆ 1 - 8 hours post-injection for osteomyelitis.
 - ◆ Diabetic feet: 4 – 8 hrs & 18 – 24 hrs.
- Planar imaging sufficient in many situations, but SPECT can be contributory to improved interpretation.

Normal Biodistribution of LeukoScan®



99m Tc-labeled (sulesomab)



- Non-Classic Acute Appendicitis
- Clinical trial to determine the presence or absence of infection or inflammation in the abdomen, especially in patients presenting with a suspicion of non-classic acute appendicitis

Passalaqua AM, et al. Diagnosing suspected acute nonclassic appendicitis with sulesomab, a radiolabeled antigranulocyte antibody imaging agent. J Pediatr Surg. 2004 Sep;39(9):1338-44.

Barron B, et al. Rapid diagnostic imaging of acute, nonclassic appendicitis by leukoscintigraphy with sulesomab, a technetium 99m-labeled antigranulocyte antibody Fab' fragment. LeukoScan Appendicitis Clinical Trial Group. Surgery. 1999 Mar;125(3):288-96.

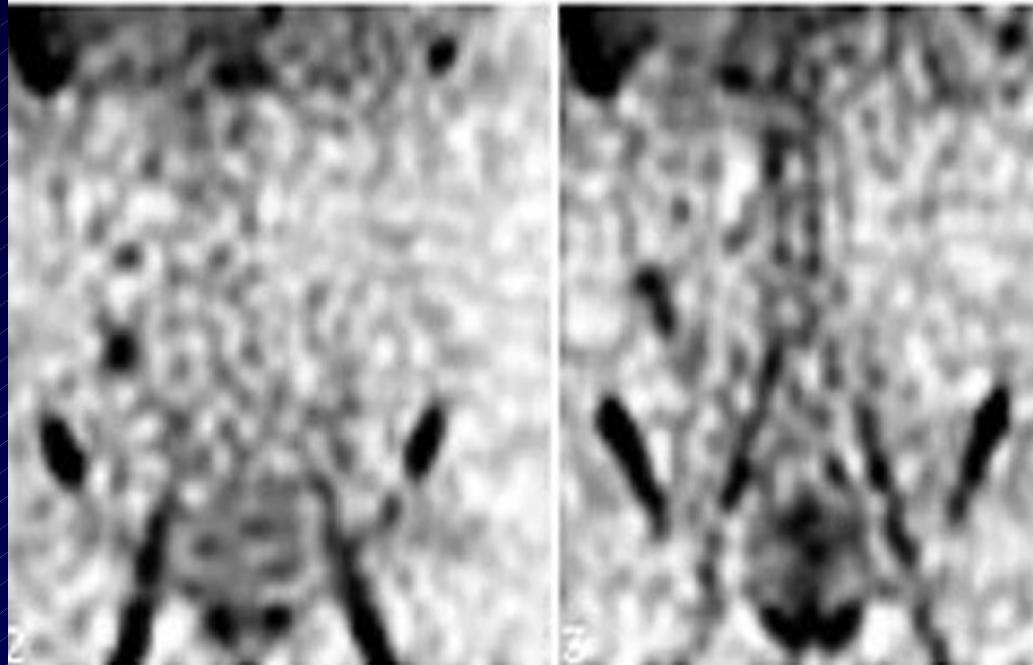
16 year-old Male

- Abdominal pain x 3 days, RLQ tenderness, nausea, vomiting, fever, WBC 19.7, ESR 15 mm/hr



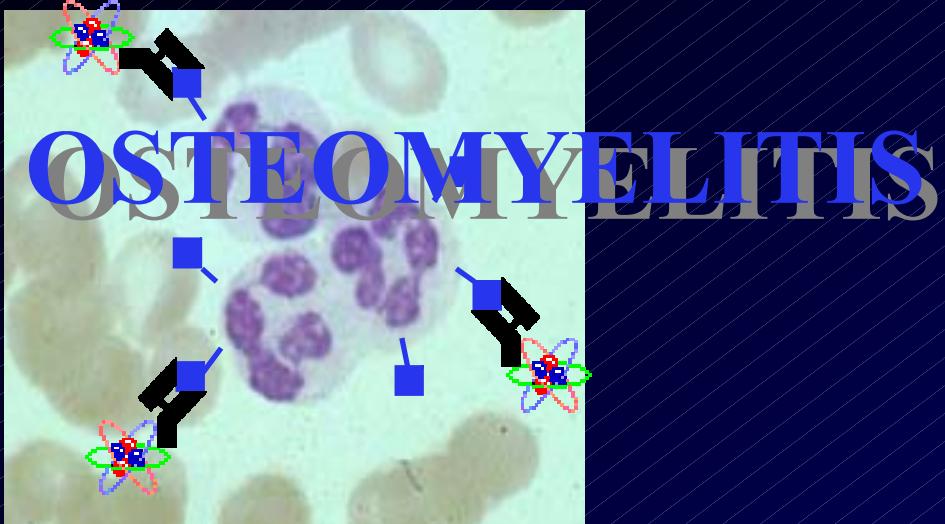
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40 Min.
Planar



1 Hour
Coronal

99m Tc-labeled sulesomab



Determine the presence, location and extent of infection or inflammation in bone and soft tissue of patients with suspected osteomyelitis, including patients with diabetic foot ulcers

Rubello D, et al. Role of anti-granulocyte Fab' fragment antibody scintigraphy (LeukoScan) in evaluating bone infection: acquisition protocol, interpretation criteria and clinical results. *Nucl Med Commun.* 2004 Jan;25(1):39-47.

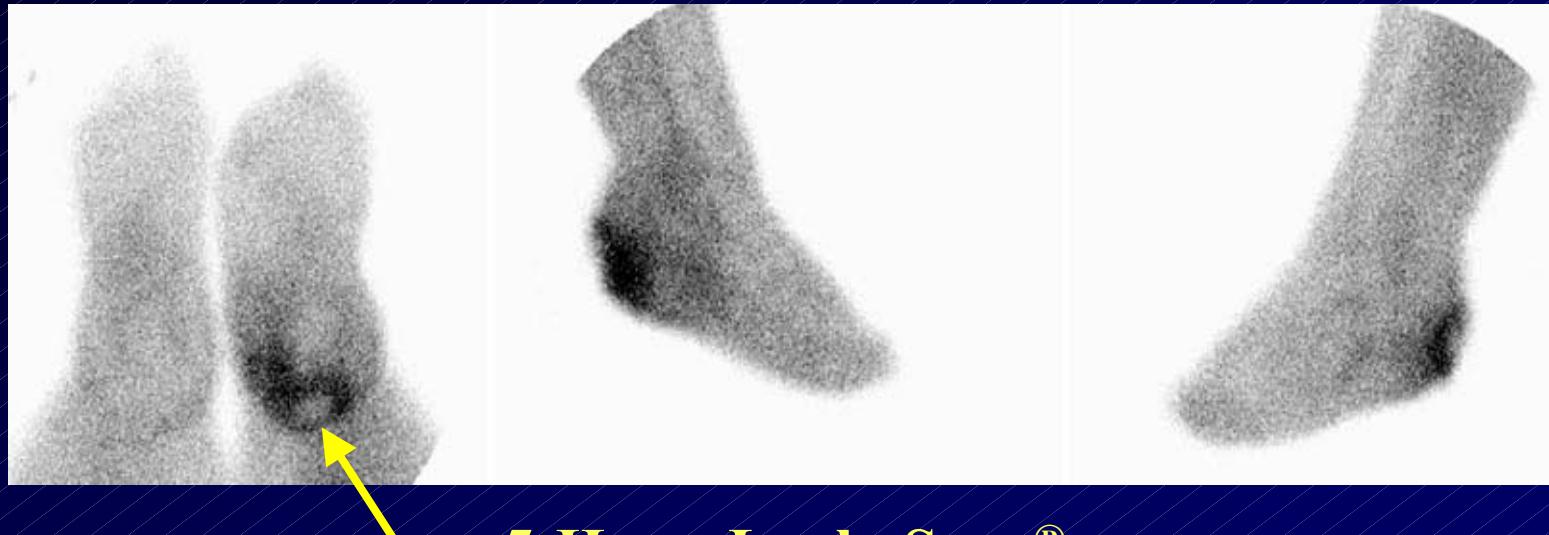
Gratz S, et al. LeukoScan for imaging infection in different clinical settings: a retrospective evaluation and extended review of the literature. *Clin Nucl Med.* 2003 Apr;28(4):267-76.

Ivancevich V, et al. Imaging of low-grade bone infection with a technetium-99m labelled monoclonal anti-NCA-90 Fab' fragment in patients with previous joint surgery. *Eur J Nucl Med Mol Imaging.* 2002 Apr;29(4):547-51. Epub 2002 Feb 23

Jimenez Heffernan A, et al. 99m Tc-labelled antigranulocyte antibody fragment Fab scintigraphy (sulesomab, leukoscan) and three-phase bone scintigraphy in the study of painful hip and knee prosthesis. *Rev Esp Med Nucl.* 2002 Jul;21(4):286-93

64 year-old Female

- Diabetes, left heel ulcer
- Status post amputation of left great toe and metatarsal head
- LeukoScan®: increased uptake in posterior aspect of left calcaneus with central photopenic area
- Left BKA: osteomyelitis; trabeculae necrotic with osteoblastic changes

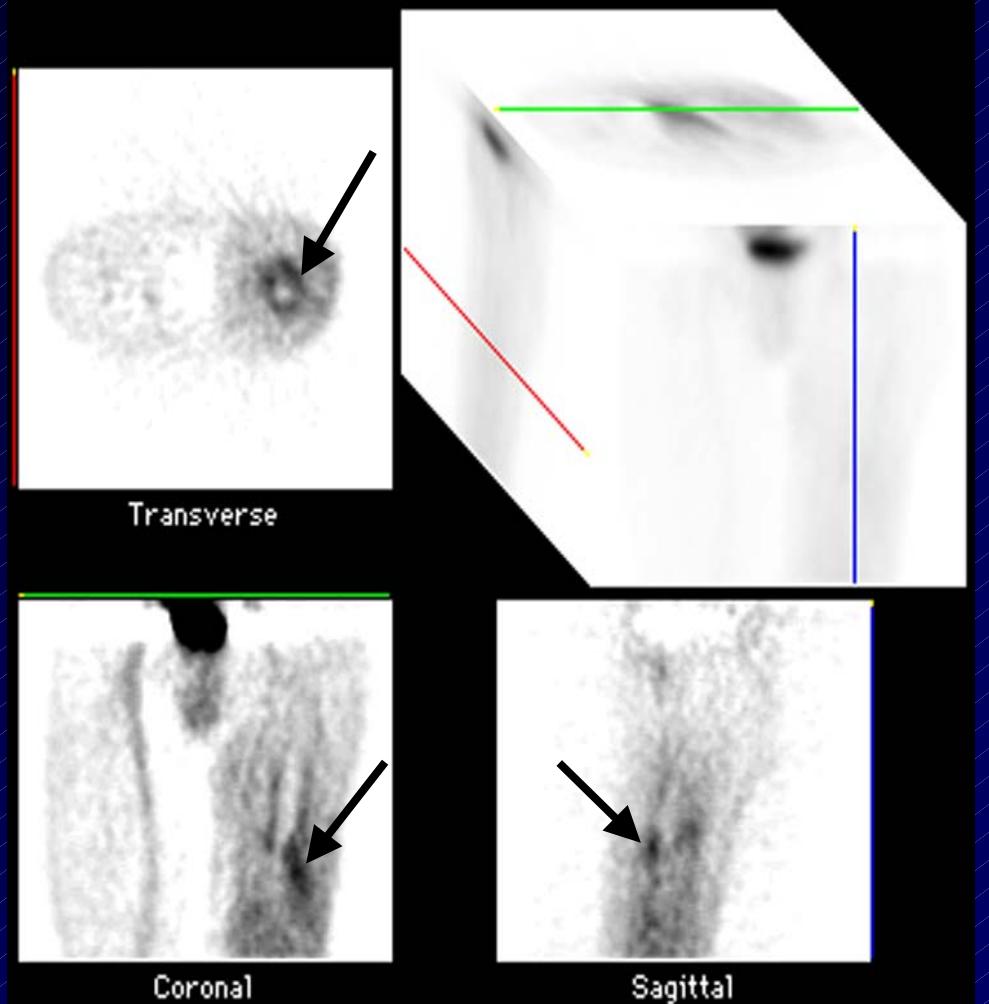


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5-Hour LeukoScan®

47 year-old Male

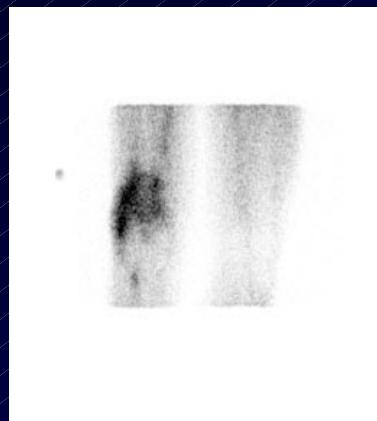
- History of non-union femoral fracture secondary to trauma
- 5-hour LeukoScan SPECT better defines abnormality as well as surrounding anatomy
- Partial diaphyseal sequestrectomy:
 - ◆ Extensive necrotic-looking granulation tissue;
 - ◆ Bone cultures grew multiple organisms consistent with osteomyelitis



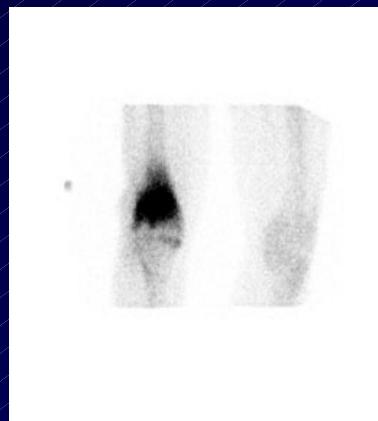
085601

Knee Abscess

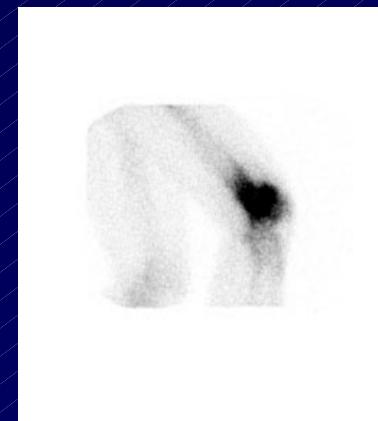
- 44 year-old male. Previous gunshot wound.
Presented with an abscess in right knee lateral side
with pain and swelling.
- 3 phase bone scan: abnormal scan consistent with
osteomyelitis in right knee lateral



Ant blood pool



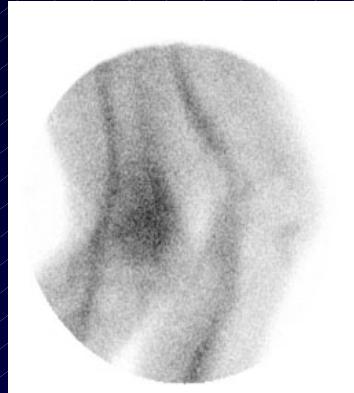
3 phase bone scan



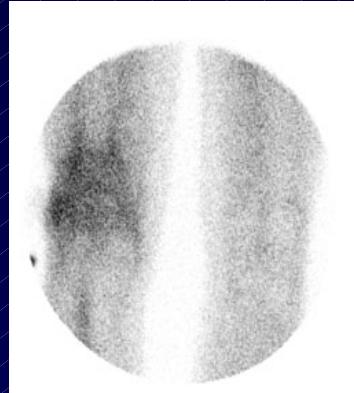
R Lat/L Med

Knee Abscess

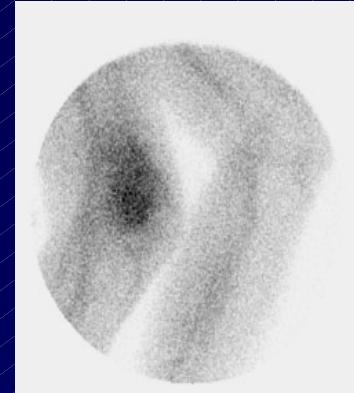
- LeukoScan: increased uptake in soft tissue particularly intense in the right ulcer site laterally, distal aspect of femur appears involved.
- Bone biopsy: osteomyelitis, distal right femur. Consistent with LeukoScan, bone scan



1-hr R Lat/L Med



7-hr Ant



7-hr R lat/L Lat

LeukoScan images

Pediatric Osteomyelitis

- 6 month-old female. Refuses to crawl, left lower swelling, pyrexia and tenderness.
- X-rays lower extremity – normal.

Lateral
left tibia

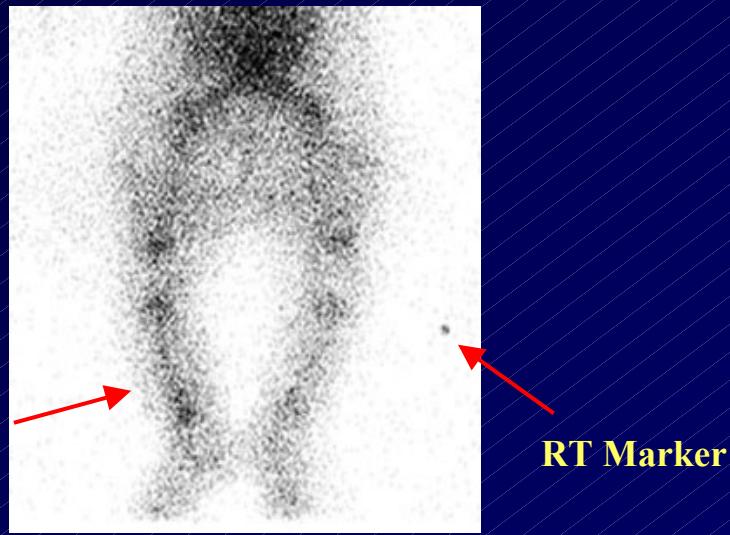


A/P
left
tibia



Pediatric Osteomyelitis

- LeukoScan: increased uptake in left distal metaphysis and femoral metaphysis, consistent with osteomyelitis.
- Patient placed on antibiotic therapy of IV Flullox and Benzyl Penicillin. Symptoms resolved.



3-hr LeukoScan

Elevated white cell count

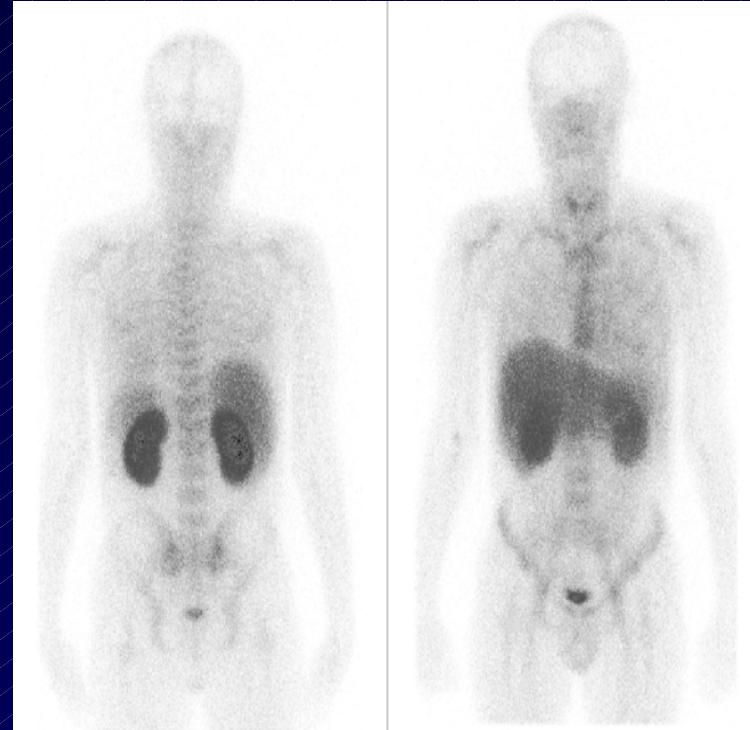
- 43 year-old male. Elevated white cell count, Chronic Anemia, Elevated platelets.
- Other investigations – negative.

Thyroditis

- LeukoScan: Marked increase in thyroid gland, not due to free pertechnetate. Suggestive of acute thyroiditis.



3 Hr planar static



3 Hr WB planar

Fever of Unknown Origin

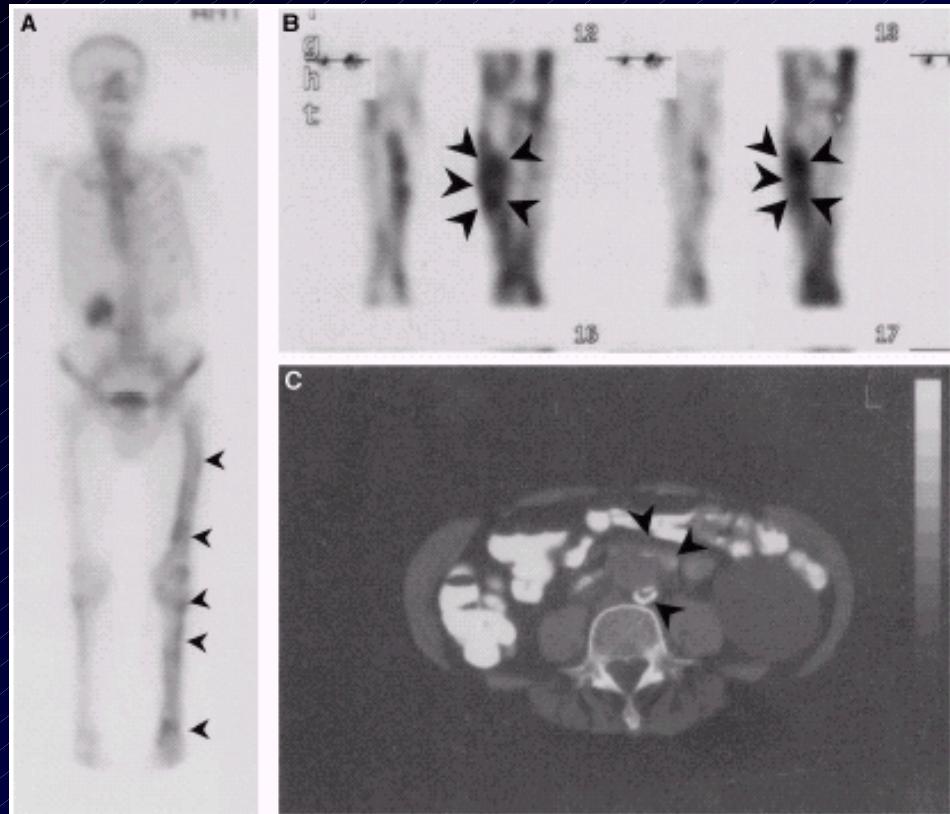
A 72-year-old man was hospitalized for fever of unknown origin (FUO) of 6 months duration. Medical history was remarkable for Leriche's syndrome and, more particularly, complete left iliac and partial right iliac artery obstructions.

The patient was treated surgically with placement of a right aortoiliac and a left aortofemoral synthetic graft, the latter repair being more extensive as a result of more severe obstruction.

Laboratory work-up for FUO was inconclusive. Bone scanning showed cortical uptake of Tc-99m MDP in the left femur and in the tibia (A, anterior view; arrowheads).

During his hospitalization, the patient reported deep pain in the left lower extremity, but physical examination was unremarkable.

Fever of Unknown Origin



Tc-99m-Tc-99m-labeled monoclonal antibody fragment (LeukoScan Immunomedics, Darmstadt) scan showed uptake in the left calf (B, anterior views; arrowheads).

Repeated blood cultures and cultures from aspirates of the abscess in the left calf yielded various pathogens

LeukoScan Product Summary

- Clinical trials show sulesomab may be useful in the diagnosis of acute non-classic appendicitis
- Publications for FUO, endocarditis and other soft tissue infections
- Sulesomab is indicated for the diagnosis of suspected osteomyelitis

References

Mecklenbeck W, et al. “Value of Immunoscintigraphy with ^{99m}Tc -Labeled Antigranulocyte Antibody Fragment (sulesomab) in Extra-Osseous Inflammation.” *JNM. 2001: 42:5 (supplement):331*

Gratz S, et al. “ ^{99m}Tc -labelled antigranulocyte monoclonal antibody FAB' fragments versus echocardiography in the diagnosis of subacute infective endocarditis.” *International Journal of Cardiology. 2000: 75: 75-84.*

Ioannis I, et al. “Tc-99m-Labeled Monoclonal Antibody Fragment Imaging in a Patient With Fever of Unknown Origin.” *Clinical Nuclear Medicine. Volume 28, Number 12, December 2003*

www.kesolid.cz

- V rámci klinického materiálu na firemním webu k dispozici 7 kazuistik pro LeukoScan / zdravotnická část - pro odbornou veřejnost - klinická kapitola /
- Lze vyhledávat i podle přípravku !
- V přípravě:
 - ◆ rozsáhlejší práce ohledně problematiky diabetické nohy (v systému jako kazuistika jediná, avšak obsahuje příklady 6 pacientů)
 - ◆ kazuistika – detekce epidurálního abscesu
 - ◆ online do konce dubna 2005, informace vždy v Novinkách

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 VÝROBKY PRO NUKLEÁRNÍ MEDICÍNU
A IN VITRO DIAGNOSTIKU

MAPA SERVERU KONTAKT ÚVOD

Přehled kazuistik << ZPĚT

kód	název
ONK-26	Zobrazení leiomysarkomu po aplikaci 99mTc sulesomabu (Leukoscan) Bradáčková, Ivana - Stejskal, Jan; 17.7.2004
SKE-24	Vyšetření pomocí in vivo značených granulocytů LeukoScan Žižlavský, Ivan; 30.7.2001
SKE-25	Zánětlivé uvolnění endoprotézy kolenního kloubu Bureš, Jaroslav; 3.12.2001
SKE-26	Osteomyelitis, diagnostika pomocí LeukoScanu Bureš, Jaroslav; 11.6.2002
SKE-27	Posttraumatická synovialitida Bureš, Jaroslav; 11.6.2002
SKE-28	Scintigrafické zobrazení spondylodiscitidy pomocí Leukoscanu Rousková, Viera; 27.5.2003
SKE-37	Chronická osteomyelitida Kraft, Otakar; 8.4.2005

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